Proposal for the design of a mechanism for the distribution of benefits derived from the utilisation of genetic resources and associated traditional knowledge

By

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ABSTRACT

Achieving a distribution of benefits derived from the use of genetic resources (GR) and traditional knowledge (TK) has proven to be a target difficult to achieve. For this reason, the objective of this thesis is to find the key elements useful for a feasible implementation of ABS. Such elements respond to the problems evidenced throughout this work regarding the difficulties experienced so far in the operationalisation of ABS. Those problems are, (i) that developing proposals for the application of legal frameworks on this very specialised, complex, fragmented, and highly political issue, requires more than one approach, (ii) that the accessible proposals on how to address ABS are predominantly theoretical, and (iii) that there seems to be resistance to the inclusion of new aspects in the discussion on ABS.

Therefore, the hypothesis of this thesis is that the experience gained by countries in the implementation of ABS laws provides practical ways to solve some of the issues related to the achievement of benefit-sharing that should be explored to complement the existing theoretical proposals. For that reason, the adoption of a practical rather than a theoretical approach has been preferred. However, solving those problems requires theoretical support. Thus, the analysis found in López, de Sousa Santos, and McCann and March have been acknowledged. From different perspectives, these authors support the creation of legal systems according to the way people behave in their daily life.

Fundamental aspects taken into consideration in the current study include the variety of conceptual recommendations aimed to achieve ABS. Another aspect is the legal frameworks and mutually agreed terms (MATs) available in the ABS Clearing House (ABSCH) of the CBD.

This work concludes that the most significant obstacles to effective implementation of ABS are: (i) the national/bilateral approach to the CBD; (ii) the lack of specific regulation for access to GR *ex-situ* in the CBD; and, (iii) the application of the concept of public domain in the ABS context. Due to the lack of agreement between the Parties concerned, these obstacles are not about to be amended soon, and, for now, possible solutions can only be sought through national laws.

This thesis considers that benefit-sharing could be better addressed if provider countries were to abandon the current schema of entering into single negotiations every time a GR or a TK is accessed. This task, together with controlling and monitoring all the different ways these resources could be used once access is granted, seems so vast that it would be very difficult to accomplish. Instead, it is suggested that a mandatory sharing of non-monetary benefits with a voluntary sharing of monetary benefits is the best solution. The sharing of benefits could be encouraged by: (i) introducing a certificate of compliance upon actual sharing of non-monetary benefits; and (ii) providing tax benefits for the sharing of monetary benefits. The use of mutually agreed terms (MATs) is recommended as a tool to facilitate dispute resolution at an international level.

Given the potential that the global multilateral benefit-sharing mechanism (GMBSM), proposed in Article 10 of the NP, has in achieving benefit-sharing, the implementation of a

basic GMBSM is suggested. Modifications of this mechanism could be introduced by the Parties as they reach new agreements.

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LIST OF ACRONYMS AND ABBREVIATIONS

ABS: Access and Benefit-Sharing
ABSCH: ABS Clearing House
AMJB: Mexican Association of Botanic Gardens (in its Spanish acronym)
BGBM: Botanic Garden and Botanical Museum
BGCI: Botanic Gardens Conservation International
BUAP: Benemérita Universidad Autónoma de Puebla
CBD: Convention on Biological Diversity
COP: The Conference of the Parties to the CBD
EU: The European Union
EPO: The European Patent Office
FAO: Food and Agriculture Organisation
GM: Genetically Modified
IGC: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
ILCs: Indigenous and Local Communities
ILO: International Labour Organisation
IP: Intellectual Property
IPEN: The International Plant Exchange Network
IPRs: Intellectual Property Rights
ISP: Internet Service Providers
ITPGRFA: International Treaty on Plant Genetic Resources for Food and Agriculture
GMBSM: Global Multilateral Benefit-sharing Mechanism
GMOs: Genetically Modified Organisms
GR: Genetic Resources
MATs: Mutually Agreed Terms
MLS: Multilateral System of FAO
MTA: Material Transfer Agreement
NP: The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity
OBGA: Oxford Botanic Garden and Arboretum
PCT: The Patent Cooperation Treaty
PIC: Prior Informed Consent
PIP Framework: Pandemic Influenza Preparedness Framework
R&D: Research and Development
SMTA: Standard Material Transfer Agreement
TK: Traditional Knowledge
TRIPS: The Agreement on Trade-Related Aspects of Intellectual Property Rights
USPTO: The United States Patent and Trademark Office

UPOV: International Union for the Protection of New Varieties of Plants
USA: The United States of America
WIPO: World Intellectual Property Organisation
WHO: World Health Organisation
WTO: World Trade Organisation

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CHAPTER 1. Introduction

The distribution of benefits derived from the use of genetic resources (GR) and traditional knowledge (TK) is a right recognised in favour of the countries and indigenous and local communities (ILCs) providing these resources. However, effective implementation has proven a task difficult to achieve, thus constituting one of the topics debated at great length within academia. Despite this, progress on practical implementation has been slow. Perhaps, this is because decisions are made in international fora where the work carried out by the academia is not necessarily taken into account, as highlighted by Vogel and Ruiz.[1] Notwithstanding this limitation, this thesis investigates the law and current application of the obligation to distribute the benefits derived from the access and utilisation of GR and TK (ABS). In particular, it focuses on the design of the global multilateral benefit-sharing mechanism (GMBSM), contained in Article 10 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (NP). Therefore, this first section introduces the topic through a literature review, and presents the proposals made by some academics for the implementation of the ABS system, in general, and of a GMBSM in specifics. Nonetheless, it should be stressed that the focus of the thesis will be on the effective implementation of ABS through the study of national laws, with the aim of identifying the key elements for the establishment of a GMBSM.

1. First approach to ABS developments and proposals

1.1 ABS: origins and scope

To understand what might be the origin of ABS, we must keep in mind that human life largely depends on natural resources and thus controlling their use is a matter of interest to both countries and industry. This could explain why sovereign rights of states over their natural resources has long been recognised by national laws and international legal instruments.

Over time, scientific and technological developments allowed the utilisation of natural resources in ways other than the known. This created the need to modernise the existing laws and generated new expectations in natural-resources-rich countries regarding the benefits they could receive from the new utilisations of their biodiversity. For this reason, and based on of such sovereign rights, the Convention on Biological Diversity (CBD) of 1992 established an obligation to share in a fair and equitable way the benefits derived from the use of GR.[2] The mention in the CBD of GR as the object of access, and the results of research and development as benefits to distribution,[3] not only reflects the above-mentioned interests, but also creates a

[1] Joseph Henry Vogel, Klaus Angerer, Manuel Ruiz, Omar Oduardo-Sierra 'Bounded openness as the modality for the global multilateral benefit-sharing mechanism of the Nagoya Protocol' in Charles R. McManis and Burton Ong (eds) *Routledge Handbook of Biodiversity and the Law* (Routledge, London and New York, 2018) 382.
[2] 1992 Convention on Biological Diversity 31 ILM (1992), 818, Article 15.1
[3] ibid, Article 15.7

distinction respecting the obligations derived from the utilisation of biodiversity. In this regard, after the CBD, the utilisation of GR results in ABS obligations while, for example, mining activities or the extraction of forest timber do not.

However, the CBD is not the first international instrument regulating the use of GR. The FAO had previously established rules on the use of plant GR. Its International Undertaking on Plant Genetic Resources (the International Undertaking) of 1983 states that 'plant genetic resources are a heritage of mankind and consequently should be available without restriction.'[4] This is a statement that reflects the way property rights over GR were traditionally perceived. That view changed, however, over time, and in 1991, the recognition of sovereign rights over plant GR were included in the International Undertaking.[5] The CBD enshrines this change, and, because its recognition goes beyond the FAO's scope, this Convention could be seen as the first international instrument destined to recognise sovereign rights of states over all GR within their frontiers. Nevertheless, in the opinion of some academics, such as Mgboji, it is an error to argue that the CBD and the FAO created a new regime of state sovereignty over biodiversity because they merely reaffirmed an inherent pre-existing right of state jurisdiction over plant life forms.[6] While this may be true, it is also true that before the CBD ABS obligations did not exist. Thus, the CBD did not create sovereignty rights over nature, but extended those existent rights to the use of 'new' elements of biodiversity; namely, GR and TK.

As was the case with regulations on the use of GR, the CBD was not the first international forum discussing the conditions under which ABS should operate. On an international level, this discussion began within the GATT and continued in other forums such as the WTO, the FAO, the WHO, and the World Intellectual Property Organisation (WIPO). Thus, the CBD is a result and a part of a process that had started earlier.

In addition to one of the CBD's objectives being the achievement of ABS,[7] the issue was also debated in other fora. As a result, there are currently three different ABS systems: i) the FAO's system, contained in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), is designed to rule on the use of plant GR for food and agriculture; ii) the WHO's system, devised in the Pandemic Influenza Preparedness (PIP) Framework, was created to regulate the use of GR for the development of vaccines in a pandemic situation; and (iii) the system of the CBD, further developed in the NP, aims to govern the utilisation of GR for all purposes different from those regulated by the FAO and the WHO. These three systems consist of a set of rules that comprise the international ABS system, which were created to

[4] FAO, International Undertaking on Plant Genetic Resources, Resolution 8/83 (1983), Article 1

[5] FAO, Annex 3 to the International Undertaking on Plant Genetic Resources. Resolution 3/91:
'The Conference, Recognizing that: (…) the concept of mankind's heritage, as applied in the International Undertaking on Plant Genetic Resources, is subject to the sovereignty of the states over their plant genetic resources, (…)
Endorses the following points: 1. that nations have sovereign rights over their plant genetic resources ; (…)'
http://www.fao.org/3/x5587E/x5587e06.htm#Resolution3, accessed 08.05.2019

[6] Ikechi Mgboji, 'Beyond Rhetoric: State Sovereignty, Common Concern, and the Inapplicability of the Common Heritage Concept to Plant Genetic Resources' (2003) 16 Leiden Journal of International Law 821, 837.

[7] CBD (n 2), Article 1

complement each other and be mutually supportive. Their relationships and characteristics are studied in Chapter 5.

The basic logic of ABS is that access to GR is subject to the prior informed consent (PIC) of the Party providing the resource and, where granted, shall be upon mutually agreed terms (MATs). On the grounds of the exercise of sovereign rights, each country, through their national laws, can determine the conditions under which ABS will operate in their territories.[8] This means that compliance with ABS obligations must be achieved by each country at a national level. This aspect is known as the bilateral/national approach to compliance with ABS obligations and, as explained in Chapter 3, it has been identified as one of the obstacles for benefit-sharing realisation.

GR are not, however, the only subject matter of ABS. The knowledge of ILCs regarding the use and management of biodiversity (called traditional knowledge -TK), and when associated with GR, also falls within the ABS scope.[9] Article 3 of the NP clarifies the issues with respect to TK.[10] Importantly, the NP creates an obligation for the countries to take into consideration customary law in the development of national law and policy.[11] Although this could be interpreted as a step forward in the protection of TK and the ILCs' rights, some authors seem less sure. For example, Tobin[12] noted that as the negotiations for the agreement on one or more instruments for the protection of TK advanced within the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC), references to customary law started to disappear from its draft instrument.

Discussions on the ABS scope do not only involve GR and TK. Matters such as by-products, derivatives, and information are also under debate. This appeared to be caused by the fact that advances in science and technology came accompanied by economic expectations on new forms of utilisation of GR and TK. For this reason, as pointed out by Oberthür and Rosendal, such advances also brought an economic incentive to introduce patent protection for biodiversity-based inventions.[13] As a result, the ABS debate was placed into the WIPO forum where the relationship between the CBD and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has been discussed for many years, as explained in Chapter 6.

To better understand this debate, it is important to stress that, despite the acknowledgement of the right to benefit from the use of GR and TK, neither the CBD nor the NP establish or recognise states' property rights over their GR or of ILCs on their TK, nor the

[8] ibid, Article 15.1, 15.5, and 15.5

[9] ibid, Preamble, and Article 8j

[10] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity (2010), Article 3

[11] ibid, Article 12.1

[12] Brendan Tobin 'Bridging the Nagoya Compliance Gap: the fundamental role of customary law in protecting of indigenous peoples' resource and knowledge rights' (2013) 9(2) Law Environment and Development Journal 142, 152.

[13] Sebastian Oberthür and G. Kristin Rosendal 'Global governance of genetic resources. Background and analytical framework' (ch 1) in Sebastian Oberthür and G. Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, New York, 2014) 4

TRIPS. For Tvedt and Schei, recognition of intellectual property rights (IPRs) over TK in international fora, such as TRIPS and the WIPO, have largely failed.[14] Oguamanam believes that this might be caused by the lack of political will of industrialized countries who benefit from continued appropriation of local knowledge, the informal/non-scientific way TK is produced, the asymmetrical relationship of power between industrialised countries and ILCs, and because IPRs are seen as a capitalist instrument which is not suited to societies that operate in a mainly communal model outside or on the fringes of the contested paradigms of the market economy framework.[15]

This clarification helps to explain why, given the lack of recognition of IPRs over GR and TK, and the poor integration of the ABS rules with the IP system, there have been some claims where IPRs over inventions using GR and/or TK could be obtained allegedly without complying with ABS obligations (PIC, MAT, and benefit-sharing). As could be predicted, this is perceived as another obstacle to ABS realisation.

Despite the apparent simplicity of ABS (mutual exchange of resources between two parties), it seems that the majority of authors agree that this system does not properly work.[16] As Oguamanam and Jain show, ABS is a complex matter containing controversial aspects such as mandatory obligations under the patent system to disclose the origin of the resources and proof that PIC was obtained.[17] The main aspects of ABS under discussion are presented below.

1.2 The problematic features of ABS

Apart from what has been already said above, the problematic aspects of ABS identified by some authors as impeding ABS operativity can be grouped in three categories: i) wrong, unclear, or insufficient definitions of the core concepts of ABS; ii) gaps between the ABS rules and reality, including the absence of rules for accessing GR *ex-situ*, progress in the

[14] Morten Walløe Tvedt and Peter Johan Schei 'The term 'genetic resources' Flexible and dynamic while providing legal certainty?' (ch) 2 in Sebastian Oberthür and G. Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, New York, 2014) 38

[15] Chidi Oguamanam, 'Local Knowledge as Trapped Knowledge' (2008) 11(1) The Journal of World Intellectual Property 29, 41.

[16] See for example: Bronwyn Parry, *Trading the Genome. Investigating the commodification of Bio-information* (Columbia University Press, New York, 2004) 11; Ruiz (n 7) 36; Oberthür and Kristin Rosendal (n 14) 2, 4; Manuel Ruiz, 'Genetic Resources as Natural Information: Implications for the Convention on Biological Diversity and Nagoya Protocol' (Routledge, New York, 2015) 33; Joseph Henry Vogel, Manuel Ruiz Muller, and Klaus Angerer, 'Submission of views in preparation for the Expert Meeting on the need for and modalities of a global multilateral benefit-sharing mechanism and the first meeting of the Compliance Committee of the Nagoya Protocol' <https://www.uni-giessen.de/fbz/fb11/institute/histor/mitarbeiter/mitarb_dwnl/IUCNAnnexsubmissionArt10.pdf> accessed 26.05.2019, 3; Graham Dutfield, 'If we have never been modern, they have never been traditional: 'traditional knowledge', biodiversity, and the flawed ABS paradigm' (ch 18) in Charles R. McManis and Burton Ong (eds) *Routledge Handbook of Biodiversity and the Law* (Routledge, London and New York, 2018) 285.

[17] Chidi Oguamanam and Vipal Jain, 'Access and Benefit Sharing, Canadian and Aboriginal Research Ethics Policy after the Nagoya Protocol: Digital DNA and Transformations in Biotechnology' (2017) v3 (1) Journal of Environmental Law and Practice 79, 89.

biotechnology field, and considerations about the public domain; and iii) the national/bilateral approach of the CBD. The next sections deal with each of these aspects.

1.2.1 Wrong, unclear, or insufficient definitions of the core concepts of ABS

Because the CBD is an instrument whose commitments are commonly expressed in aspirational terms, many criticisms relate to its lack of clarity. This becomes particularly problematic for the core concepts of ABS as they aim to determine to whom, when and how an ABS obligation arises. For example, Tobin highlights the ambiguity of the NP in relation to when PIC is required[18] and the difficulties in knowing when ILCs have an established right to GR, when these resources are held by those communities, and when TK is associated with a GR.[19] In addition, Ruiz mentions that providers have been told what type of benefits can be expected, but not how much to expect in those up-front payments,[20] and Tvedt points out that the NP neither attempts to specify what is meant by 'fair and equitable' in a substantive manner nor does it establish any procedural standard to this effect.[21]

Given this, a large proportion of the studies conducted on ABS focus on re-defining its concepts. As these concepts are further explored in Chapter 4, the following is only a summary of two of the main concepts of ABS: GR and TK.

A. Genetic resources

Article 2 of the CBD describes GR as any material of plant, animal, microbial, or other origin containing functional units of heredity. A good deal of the criticism of this concept is directed towards identifying the insufficiency of its scope, while others stress that given its inadequacy, there is a case for a new definition. On the first point, Chaparro points out that the concept of GR, apart from containing an artificial separation between biological and genetic resources, is based on classical notions of genetics that restrict the interpretation of its use to the application of molecular tools. Therefore, he advocates an extended interpretation of the concept of the CBD.[22] Similarly, Schei and Tvedt suggest that an international ABS regime

[18] Brendan Tobin, 'Bridging the Nagoya Compliance Gap: the fundamental role of customary law in protecting of indigenous peoples' resource and knowledge rights' (2013) 9(2) Law Environment and Development Journal 142, 148.
[19] ibid 148.
[20] Manuel Ruiz 'The Museum as a Vehicle for Considered Judgements on Access and Benefit Sharing' in Joseph Henry Vogel (ed) *The Museum of Bioprospecting, Intellectual Property, and the Public Domain: A Place, A Process, A Philosophy* (Anthem Press 2010) 34.
[21] Morten Walløe Tvedt, 'Beyond Nagoya: Towards a legally functional system of access and benefit sharing' (ch 9) in Sebastian Oberthür and G. Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, New York, 2014) 163.
[22] Alejandro Chaparro Giraldo, 'Definiciones de Acceso a Recursos Genéticos en la Legislación Colombiana y sus efectos en la Investigación Científica' (2016) 21 Acta Biológica Colombiana 305, 305-306.

could incorporate a broad and dynamic understanding of the GR concept.[23] On the other hand, Tvedt highlights the fact that the difference between accessing a biological resource and a GR is in its use, for which he considers that benefit-sharing should be due as soon as the use has resulted in a product and revenue starts flowing.[24]

From a different perspective Vogel and others, suggest that the concept of GR in Article 2 of the CBD does not fit the cutting-edge and high-tech field of, for example, 'synthetic biology,' whose very essence will be deployed when considering GR as a 'material'.[25] In their view, there is a misconception of GR, for which they recommend the creation of a new definition. They propose that, because the object of R&D is the information of GR, the field of economics appropriate for ABS is the economics of information.[26] Thus, based upon Samuelson and Nordhaus' assertion that information is costly to produce but cheap to reproduce, they consider that GR are costly to access but cheap to replicate.[27] In their understanding (and that of other authors such as Oldham, Hall, and Forero), only by redefining GR from 'material' to 'natural information' could fairness and equity be achieved in ABS transactions.[28] For Oldham, conceiving GR as natural information is also supported by the fact that GR can be expressed as information, as proven by the current trends in the genomic sector, suggesting a decreasing dependence on physical transfers of biological materials and an increasing tendency towards electronic transfers.[29] For Ruiz, identification of natural information as the object of access allows national laws to include any natural substance extracted from a biological source or their biochemical or genetic composition through the use of biotechnology within ABS obligations.[30]

Moreover, Vogel and others suggest that when considering GR as natural information, GR are transboundary resources; and, for that reason, the ABS system should be based on a GMBSM rather than on the bilateral approach established through national or local laws. This idea has been criticised, for example, by D'Alessandro, in whose opinion, within the context of the NP, GR are not species, subspecies or any other taxonomic entity, or information, but tangible matter. He considers that GR as material cannot occur in two or more countries at the same time and, consequently, the bilateral approach is probably applicable in most cases, as

[23] J. Schei and M.W. Tvedt, 'Genetic resources in the CBD: The wording, the past, the present, and the future' (2010) FNI Report, in Ruiz (n 17) 13.
[24] Tvedt (n 21) 159.
[25] Vogel and others (n 1) 388.
[26] ibid, 377.
[27] ibid
[28] ibid; Joseph Henry Vogel and Manuel Ruiz, 'Wronged by the Wrong Language: The International Regime on Access and Benefit-Sharing' (2010) BIORES <https://www.ictsd.org/bridges-news/biores/news/opinion-wronged-by-the-wrong-language-the-international-regime-on-access> accessed 03.02.1029; P. Oldham, S. Hall and O. Forero, 'Biological Diversity in the Patent System' (2013) 8(11) PLoS ONE, in Joseph Henry Vogel, Manuel Ruiz, and Klaus Angerer (n 17) 1.
[29] P. Oldham, 'Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology' (2004) Submission to the Executive Secretary of the Convention on Biological Diversity. Centre for Economic and Social Aspects of Genomics. United Kingdom, in Ruiz (n 17) 13.
[30] Ruiz (n 16) 15-16.

in principle it should always be possible to determine the source of a specific material.[31] Similarly, for Ibañez de Novion, the understanding of GR as natural information is not coherent within the content of the CBD.[32]

Opposing the views perceiving the inadequacy of the GR concept, for Tvedt and Schei, the GR concept set out in the CBD is robust enough to grasp GR utilisation in a changing technological context,[33] while for Oberthür and Rosendal, the scope of the NP includes derivatives.[34]

B. Traditional Knowledge

To date, no consensus exists on the concept of TK, and the inclusion of accessible TK in the ABS scope generates much debate. To some scholars, widely disseminated TK should be free to be used,[35] while, for others, its use generates benefit-sharing obligations.[36] Given the existence of different national negotiating positions at present, it appears that TK related issues could only be solved case-by-case through the application of national laws.

There are many proposed concepts for TK. In general terms, they refer to the close link between the traditional lifestyles of ILCs, the traditional context in which TK is created, and the importance of this knowledge for the livelihood of ILCs and for the preservation and sustainable use of biodiversity (this is explained in Chapter 4). Additionally, in a similar way to Vogel, who views GR as natural information, Tobin and Ruiz consider TK is also information, more precisely, shared and widely disseminated.[37] In Ruiz's view, the cultural context in which TK develops and the apparent inability of classic IP tools to provide appropriate protection, make this knowledge different from other forms of shared and disseminated information.[38]

Despite the acknowledgement of the beneficial effects of TK for biodiversity, the establishment of ABS obligations for the access and use of TK face some degree of resistance. This might be because the obligation is found in Article 8j (on *in-situ* conservation) rather than in Article 15 (on access to GR and benefit-sharing) of the CBD, where it should belong. Although Article 3 of the NP completely removes the doubts that may exist in that regard, controversy has been sustained by moving the debate onto more detailed aspects of TK. Hence, it is possible to find in the specialised literature many terms created for the identification of the

[31] Vogel and others (n 1) 383.
[32] ibid 384.
[33] Tvedt and Schei (n 14) 29.
[34] Oberthür and Kristin Rosendal (n 13) 7.
[35] Dutfield (n 16) 285.
[36] Enrique Sánchez, María del Pilar Pardo, Margarita Flores and Paola Ferreira, *Protección del Conocimiento Tradicional. Elementos Conceptuales para una Propuesta de Reglamentación – el Caso de Colombia* – (Instituto de Investigación de Recursos Biológicos von Humboldt, Bogotá, 2000) 275-276.
[37] Tobin (n 12) 145; Manuel Ruiz, 'The legal protection of widely shared and dispersed traditional knowledge' in Daniel F. Robinson, Ahmed Abdel-Latif and Pedro Roffe (eds) *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge, London, New York, 2017), 124-126.
[38] ibid, Ruiz.

'many types' of TK that raise questions about whether those 'different types' fall within the ABS scope or not. For instance, Young proposes that ABS should only apply to TK where it is useful for preservation and conservation of biodiversity, because the CBD only pertains to respect, preservation, and maintenance of biodiversity.[39] Similarly, Dutfield suggests that TK in the public domain or widely distributed cannot be part of ABS, and that any demand of property rights over such TK by a government is a 'de facto nationalisation of common knowledge whose distribution may not even be confined to any country anyway.'[40]

Overall, it can be said that in an ABS context the use of TK is not confined to biodiversity preservation and its sustainable use, as is the case, for example, of traditional medical knowledge, whose importance and need for protection have been extensively recognised by the WIPO[41] and the WHO.[42] Moreover, neither the CBD nor the NP provide the right to benefit from the use of TK to the level of disclosure of this knowledge. Particularly, the way in which TK has been widely disseminated, which erroneously has been understood as one way in which TK can become a part of the public domain, cannot be ignored. Specifically, some demands of ILCs relate to the way they did lose control over their TK and their consequent inability to benefit from its use. What lay behind these claims is a valid vindication of the rights which they have been denied since and as a result of colonialism. In other words, ILCs have never had a chance to benefit from the economic use of their TK or prevent others from using it without their authorisation. In this regard, it could be argued that society owes a legal debt to ILCs. On this issue, Oguamanam adds that ILCs' reclamations are not only based on the fact that they are denied basic compensation, but also they are unable to afford the resulting drugs, seeds, or agricultural products that emerge from the resources they provide.[43] Given this, for some it is difficult to accept that it is fair and equitable to exclude widely disseminated TK from ABS when the impossibility for ILCs to benefit from the TK over which they have lost control is precisely one of the causes that motivated the creation of ABS obligations regarding TK.

Although many scholars and policy-makers could agree with the recognition of IPRs over ILC creations, including TK, its materialisation in one or more international agreements seems unlikely in the short term. For instance, Oguamanam observes that the exclusion of TK from IPRs has historically taken root in TRIPS,[44] and shows that more than one author (e.g.

[39] Tomme Young, 'Clearing the Air: Applying the Intellectual Property Framework to Individual, Community, and National Rights in The Convention on Biological Diversity' in Joseph Henry Vogel (ed) *The Museum of Bioprospecting, Intellectual Property, and the Public Domain: A Place, A Process, A Philosophy* (Anthem Press 2010) 51.

[40] Dutfield (n 16) 285.

[41] See for example: WIPO. Intellectual Property and Traditional Medical Knowledge. Background Brief No. 6. <https://www.wipo.int/export/sites/www/tk/en/documents/pdf/background_briefs-e-n6-web.pdf> accessed 22.05.2019

[42] Carlos Correa, 'Protection and Promotion of Traditional Medicine, Implications for Public Health in Developing Countries' (2002) <https://apps.who.int/medicinedocs/pdf/s4917e/s4917e.pdf> accessed 22.05.2019

[43] Chidi Oguamanam, 'Genetic Resources & Access and Benefit Sharing: Policies, prospects and opportunities for Canada after Nagoya' (2011) 22(2) Journal of Environmental Law and Practice 87, 104.

[44] Oguamanam (n 15) 40.

Brown, Arewa, Osborne, and Sunder) oppose the recognition of property rights over TK.[45] Because of this difficulty, it is advisable that regulations on ABS of TK should not be linked to the recognition of IPRs over TK.

1.2.2 Gaps between ABS and reality

ABS seems not to reflect reality accurately, as many scholars have noted. Some of the main issues identified by the literature are as follows.

A. Implementation

Obstacles to ABS implementation have been extensively discussed. A problem that particularly draws attention is that politicians and policymakers do not seem to be listening to the recommendations developed by the academia.[46] Vogel has called this the 'tragedy of unpersuasive power'.[47] As an example, Vogel and others describe how the Secretariat of the CBD conducted an on-line discussion group in 2013, where opinions should have been based on peer-reviewed articles or other reliable sources.[48] The report published by the Secretariat: 'Synthesis of the On-line Discussions on Article 10 of The Nagoya Protocol on Access and Benefit-sharing' did not include most of the elements discussed by the experts on that occasion.[49] In the same line, Vogel and Ruiz highlight that, for example, GR references within the economics of information were excluded from such reports, and that, so far, references to GR as natural information have never been considered within the official agenda of the COP.[50] Tobin, for his part, warns that under WIPO, customary law references have been deleted or replaced with the term 'cultural norms', which is unknown in international law.[51] Although he sees in customary law an important opportunity for ILCs to influence the nature of national and international regulations of TK,[52] there is room for doubt regarding the ability of ILCs to modify national and international laws.

Additionally, Tobin notes that efforts on ABS implementation tend to focus on the establishment of 'due diligence' requirements for users of GR and TK. For him, this concept should include compliance with customary law in the countries where ILCs have the jurisdiction to govern access to their GR and TK.[53] He, therefore, considers it a weakness that the European

[45] ibid, 42-43.
[46] Vogel and Ruiz (n 28).
[47] Joseph Henry Vogel, 'The Tragedy of unpersuasive power: The Convention on Biological Diversity as Exemplary' 5(4) International Journal of Biology, 44-54 in Vogel and others (n 1), 389.
[48] ibid, 382.
[49] ibid, 387.
[50] ibid; Ruiz (n 20) 37.
[51] Brendan Tobin, 'Where custom is the law: state and user obligations to 'take into consideration' customary law governing traditional knowledge and genetic resources' (ch 19) in Charles R. McManis and Burton Ong (eds) *Routledge Handbook of Biodiversity and the Law* (Routledge, London and New York, 2018) 297.
[52] ibid, 303-304.
[53] ibid, 302.

legislation makes no reference to customary law, and only extends protection to TK that is legally protected in the country of origin.[54]

For their part, Nijar, Posey and Dutfield, and Laird and Noejovich, consider that TK protection is crucial for achieving ABS of both GR and TK.[55] Although this might be true, it should not be forgotten that after almost twenty years of intense work within the WIPO, no agreement on one or more instruments for the protection of TK has been achieved. Given this, it seems reasonable to propose that the design of any ABS mechanisms for TK should not be subject to TK protection or the recognition of IPRs over this knowledge.

B. Contradictions in the arguments against the distribution of benefits

As McGraw[56] and Rosendal[57] have both pointed out, the commercial value of GR is in itself greatly disputed. For instance, Grajal has shown that user countries and corporations tend to hold the view that bioprospecting is not profitable enough for sharing its benefits, while criticising ABS legislation in provider countries for allegedly undermining access and innovation efforts.[58] This position seems contrary to the figures provided by authors such as ten Kate and Laird,[59] Gehl Sampath,[60] and Swanson[61] about the economic impact of GR. As the figures show (in Section 3.2 of Chapter 7), developed industrialised countries appear to be the main beneficiaries of the commercial use of biodiversity. As an example, the UNDP demonstrates that, at the time the CBD was negotiated, provider countries only had about 1% of all patents in biotechnology.[62] For Tvedt and Schei, the great expectations in the business community regarding what bio-economy could achieve sharply contrasts with the views of business

[54] ibid, 293-294.

[55] G.S. Nijar, *In Defence of Indigenous Knowledge and Biodiversity: A Conceptual Framework and Essential Elements of a rights Regime* (Third World Network, Biodiversity Convention Briefings, TWN Penang, 1996); D.A. Posey, G. Dutfield, *Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities* (International Development Research Centre, Ottawa, 1996); S. Laird, F. Noejovich 'Building Equitable Research Relationships with Indigenous Peoples and local communities', in S. Laird (ed) *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*, (Earthscan. London and Sterling, VA, 2002), in Tobin (n 51) 291.

[56] D.M. McGraw, 'The Story of the Biodiversity Convention: Origins, Characteristics and Implications for Implementation' in P.G. Le Preste (ed) *Governing Global Biodiversity: The Evolution and Implementation of the Convention on Biological Diversity* (Al-dershot, UK: Ashgate, 2002) in Oberthür and Kristin Rosendal (n 13) 3.

[57] G.K. Rosendal, 'Balancing Access & Benefit-Sharing and Legal Protection of Innovations from Bioprospecting: Impacts on Conservation of Biodiversity' (2006) 15(4) Journal of Environment and Development 428,447 in Oberthür and Kristin Rosendal (n 13) 3.

[58] A. Grajal 'Biodiversity and the Nation State: Regulating Access to Genetic Resources Limits Biodiversity Research in Developing Countries' (1999) 13(1) Conservation Biology 6, 10 in Oberthür and Kristin Rosendal (n 13) 3.

[59] K. ten Kate, S.A. Laird, The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-sharing, (Earthscan, London, 1999) in Oberthür and Kristin Rosendal (n 13) 3.

[60] P. Gehl Sampath, Regulating Bioprospecting: Institutions for Drug Research, Access and Benefit-sharing (United Nations University, New York, 2005) in Oberthür and Kristin Rosendal (n 13) 3.

[61] T. Swanson, *Intellectual Property Rights and Biodiversity Conservation* (Cambridge University Press, 1995) 59 in Oberthür and Kristin Rosendal (n 13) 3.

[62] UNDP, *Human Development Report* (United Nations Development Programme, New York, 2005) in Oberthür and Kristin Rosendal (n 13) 4.

representatives to the CBD, who often stress that the value of GR is low.[63] Brand, Rosendal, and others see this imbalance as foundational for the North-South conflict that has structured international ABS politics since the beginning.[64]

From a different point of view, Vogel and others claim that when value has been added to natural information (GR) and the associated IPRs have expired, any future value added to the same natural information should not fall under an ABS obligation.[65] This idea is similar to the existent prohibition of second use patents in some jurisdictions. Although this might be a practical solution for ABS operativity, it should not be forgotten that ABS obligations originate each time a GR is used, regardless of the value added by a previous utilisation of the same GR. Also, this generates economic expectations in some provider countries, and is perhaps why, for example, the inclusion in the ABS scope of continued uses of GR collected before the CBD is one of the matters currently under discussion. Nevertheless, only the states can take these kinds of decisions as only they can regulate ABS within their jurisdiction. Unless an agreement is reached at the international level, many different positions can be found in this regard.

C. GR *ex-situ*

While many authors have drawn attention to the potential risk posed by ABS obligations to academic research[66], especially given that many of the materials used for such purposes were collected before the CBD entered into force[67], it should not be overlooked that: (i) the collection of GR for such purposes is still ongoing; (ii) that not all *ex-situ* GR, whenever collected, are in fact used exclusively for non-commercial research purposes; and (iii) that non-commercial uses in any event remain within the scope of ABS, which can readily be implemented in such cases through the sharing of benefits in non-commercial form. Because of this, they suggest that a system for academic non-commercial research should be of free access and involve non-monetary benefits, and that the sharing of economic benefits might be assured via a decoupled funding mechanism through the GMBSM.[68] To secure compliance, they recommend using a common standard/set of guidelines/code of conduct, which should be complemented by a top-down political process at the level of the NP, flagging minimum requirements, such as control measures and temporal scope.[69] However, as explained in Section 3.1.5 of Chapter 3, the NP contemplates the creation of simplified ABS processes for

[63] Tvedt and Schei. (n 13) 19.
[64] U. Brand, C. Görg, M. Wissen, *Conflicts in Environmental Regulation and the Internationalisation of the State. Contested Terrains* (Routledge, London and New York, 2008) in Oberthür and Kristin Rosendal (n 13) 3; G.K. Rosendal, *The Convention on biological Diversity and Developing Countries* (Dordrecht, the Netherlands: Kluwer Academic Publishers, 2000) in Oberthür and Kristin Rosendal (n 13) 4.
[65] Vogel, Ruiz, and Angerer (n 16) 2.
[66] Susette Biber-Klemm, Kate Davis, Laurent Gautier and I. Martinez Sylvia, 'Governance options for *ex-situ* collections in academic research' (ch 12) in Sebastian Oberthür and G. Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, New York, 2014) 213, 215.
[67] ibid, 217.
[68] ibid, 224.
[69] ibid, 227.

non-commercial scientific research. Thus, the problem with this matter would be the lack of legal developments to regulate it rather than difficulties arising from the provisions of CBD or the NP.

For their part, Dedeurwaerdere and others consider that GR in *ex-situ* conditions are de facto transboundary, since GR *ex-situ* are typically shared 'amongst many researchers in transboundary situations', i.e., researchers located in different jurisdictions. Thus, access to *ex-situ* GR should be treated as access to resources in a transboundary situation.[70]

D. Synthetic biology

The CBD and the NP were not designed for digital resources. Technological developments allow, however, the use of digital tools in research activities using GR information. As Bagley shows, this raises concerns about sequenced information being made freely available in online databases, because, allegedly, this practice leads to what has been called 'digital misappropriation' or 'digital biopiracy' of GR.[71] In this regard, the NGOs ETC Group and Friends of the Earth note, for example, that the difference between 'traditional' and 'digital' biopiracy is that the latter allows one to take DNA sequences from databases to transfer them digitally to a DNA synthesiser to be copied and re-built elsewhere without the need of ABS agreements, because no physical material is transferred.[72] For Pottage, this may create reluctance on the part of provider countries to enter into non-commercial agreements due to the possibility of digitalising GR information that could be later used for the development of lucrative ABS-free modified organisms and products for commercial applications.[73] Thus, many have raised doubts about the rights applicable to synthetic biology parts and information.

There are two sides to this issue, as Bagley shows. The first considers synthetic biology-engineered parts and information as open sources that should be disclosed, shared, and be freely accessible; the second sees patent protection as a beneficial incentive for development. As she points out, both of these approaches are being pursued by researchers, freely distributing certain novel sequences, while seeking patent protection for more commercially viable outputs.[74] For Torrance, the focus on open sources as an option to regulate access to

[70] Tom Dedeurwaerdere and others, 'Governing Global Scientific Research Commons under the Nagoya Protocol' (ch 13) in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges* (Legal Studies on Access and Benefit-sharing, v. 1, BRILL Nijhoff 2012), 418.

[71] Margo A. Bagley, 'De-materializing genetic RESOURCES Synthetic biology, intellectual property and the ABS bypass' (ch 15) in Charles R. McManis and Burton Ong (eds) *Routledge Handbook of Biodiversity and the Law* (Routledge, London and New York, 2018) 227.

[72] SynBioWatch, '101 Fact Sheets from Friends of the Earth' (2013). <http://www.synbiowatch.org/2013/05/synthetic-biology-101-some-technical-details-from-friends-of-the-earth/> in Bagley (n 71) 227.

[73] A. Pottage, 'Too Much Ownership: Bio-Prospecting in the Age of Synthetic Biology' (2006) 1(2) Biosocieties 137, 158 in Bagley (n 71) 227.

[74] Bagley (n 71) 222.

GR information reflects some interest in granting copyrights instead of patent rights, as copyright protection may produce a more 'socially desirable balance' of permitted versus restricted uses of DNA sequences.[75] On this matter, Rai and Boyle suggest the use of 'copyleft licences'[76] as a way to impose sharing requirements on users.[77] This is a position criticised, by Holman, Karjala, Torrance and Kahl, Murray, and others, as copyright is a poor fit for synthetic biology, because sequences are generally dictated by the desired function they are to perform rather than by the author's express choices.[78]

Due to the challenges posed by copyright and patent law for the protection of synthetic biology, Samuelson, Rai and Boyle argue that a *sui generis* IP regime might be most appropriate.[79] Additionally, Bagley considers that countries could include digital information and products derived therefrom into ABS through national laws, but recognises that compliance in this case is likely to be significantly more challenging than for tangible GR materials.[80] She also criticises the proposal of Yamamoto and others of watermarking DNA, considering that (i) this process may not be economically feasible or efficient for large quantities of DNA sequences; (ii) watermarks may be susceptible to degradation; and, (iii) it may be possible for third parties to identify and remove watermarks.[81]

Finally, for Vogel and others, the reluctance to include digital information under a definition of synthetic biology, as a shift in the understanding of what constitutes a GR, as for example in the USA position, could be seen as a defence of the conceptual status quo.[82]

E. The public domain

The public domain is a legal category describing a situation in which immaterial goods are not protected under IPRs. The most common path for goods to become a part of the public domain is through the expiration of the term of protection. The public domain could be

[75] A. Torrance, 'DNA Copyright' (2011) 46 Valparaiso University Law Review 1-41 in Bagley (n 71) 222-223.
[76] 'Copyleft licences' or 'creative commons licences' are a system of licences built on the copyright law and principles to legally share knowledge and works. More information available in: https://www.copyleft.org/, and https://creativecommons.org/licenses/
[77] A. Rai, J. Boyle, 'Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons' (2007) 5(3) Plos Biology 58 in Bagley (n 71) 223.
[78] C. Holman, 'Copyright for Engineered DNA: An Idea Whose Time Has Come?' (2011) 113 West Virginia Law Review 699; D. Karjala, 'Protecting Innovation in Computer Software, Biotechnology and Nanotechnology' (2011) 16 Virginia Journal Law and Technology 55-61' A. Torrance, L. Kahl, 'Bringing Standards to Life: Synthetic Biology Standards and Intellectual Property' (2014) 30 Santa Clara High Technology Law Journal 226-227; M. Murray, 'Post-Myriad Genetics Copyrighted of Synthetic Biology and Living Media' (2014) 10 Oklahoma Journal of Law and Technology 106-111 in Bagley (n 71) 223.
[79] P. Samuelson, 'Are Gardens, Synthetic DNA, Yoga Sequences, and Fashions Copyrightable?' (2013) <http://law.scu.edu/wp-content/uploads/Samuelson-Gardens-DNA-Yoga-Fashion-Abstract.pdf>; A. Rai, J. Boyle, 'Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons' (2007) 5(3) Plos Biology in Bagley (n 71) 223.
[80] Bagley (n 71) 228.
[81] N. Yamamoto, H. Kajiura, S. Takeno, N. Suzuki, Y. Nakazawa, 'A Watermarking System for Labelling Genomic DNA' (2014) in K. Aoki (ed). Plant Biotechnology, in Bagley (n 71) 227-228.
[82] Vogel and others (n 1) 388-389.

understood as a common pool of immaterial goods of free access and use by anyone. Maybe because of this, it is commonly and erroneously understood that accessible GR and TK are in the public domain. This is the case of *ex-situ* GR and widely disseminated TK. Since the question of GR *ex-situ* has already been discussed, the following paragraphs focus on widely disseminated TK.

As Oguamanam points out, Brown supports the idea that TK is in the public domain because culture is not static and gives rise to creative mixing. He reasons that it is not possible to demarcate TK creation, and claims that doing the opposite could pose a threat to the public domain.[83] In this regard, Oguamanam argues that, if ILCs' claims to IPRs are accepted as a threat to the public domain, the same assumption should be made regarding the patenting of information or insights from the ILCs by second comers to their cultural process.[84] He notes that during the last decades the public space has been enclosed by private proprietary claims, while a re-conceptualisation of IPRs over TK has been assumed as a part of the public domain.[85] For Okediji, reluctance to recognise IPRs over TK may be caused by fears of possible threats that recognition of new categories of property could pose to the interests of existing property rights, which could alter the competitive landscape for the long run. She notices, for example, that in the WIPO draft Articles for the protection of TK, insertions of the public domain appear principally to curtail the scope of TK that could be subject to entitlement claims by resource holders.[86] Because of this, Okediji sees the public domain as a tool for denying IPRs in GR, TK, and traditional cultural expressions, which, for her, is both incomplete and inconsistent with the underlying logic of most property regimes, including the IP system.[87] In her opinion, public access and private ownership are not incompatible. However, she acknowledges the need to identify first whose interests such a customised public domain would serve, as currently, it appears that defining the public domain is about protecting existing beneficiaries of the IP system.[88]

Because TK is a different type of immaterial good located somewhere between the private and the public spheres, a re-definition of the public domain when applied to TK has been proposed. To construct a new category of public domain, Okediji proposes to begin by using the various degrees of 'publicness' of TK: secret/sacred/closely held and widely-diffused TK. For widely-disseminated TK, she suggests unfettered access with rights of attribution or other form of acknowledgement, and for secret TK, to create a system of limitations and exceptions using a three-step mechanism.[89] McCook, for his part, suggests a three-tier system

[83] Oguamanam (n 15) 43.
[84] ibid, 44-45.
[85] ibid, 45.
[86] Ruth Okediji, 'Negotiating the public domain in an international framework for genetic resources, traditional knowledge and traditional cultural expressions' in Daniel F. Robinson, Ahmed Abdel-Latif and Pedro Roffe (eds) *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge, London, New York, 2017), 141.
[87] ibid, 146.
[88] ibid, 150-151.
[89] ibid, 151-153; Ruth Okediji, 'Traditional Knowledge and the Public Domain' (CIGI Papers no 176 - June 2018, Centre for International Governance Innovation) 13. 14-15.

in which the top tier, sacred, secret, and closely held TK, would be given the highest level of protection, requiring PIC and MAT for its use. A second tier addresses publicly available but not widely distributed TK, for which only MATs are required. At the lowest tier, widely-shared TK would be freely usable, subject to protection of moral rights, with benefit-sharing to be done by a payment of user fees to a state fund.[90] Similarly, taking the experience of ILCs in Australia, Raven states that there is not one but rather a number of different, overlapping public domains, where the sharing of TK does not necessarily mean an intention that the relevant information should become a part of the global public domain.[91]

Despite the initiatives for a re-definition of the public domain, reform progress has been slow, as stated by Biber-Klemm, Davis, Gautier, and Martinez Sylvia.[92] However, for Okedij, efforts to treat TK as falling within the public domain have fallen short, not only because the concept's rhetoric and analogies are incomplete and imprecise, but also because a monolithic conception of the public domain obscures the variegated ways in which property rights are constructed to achieve specific societal outcomes.[93] In any case, as Tobin noted, benefit-sharing of TK in the public domain is valid when agreed in MATs.[94]

1.2.3 National/bilateral approach

Most authors identify this as a factor obstructing ABS implementation. Its practical implementation is explained in Section 2 of Chapter 3. Two issues have been identified as the most problematic: the many different approaches to ABS in national laws,[95] and the difficulties in enforcing MAT obligations in different jurisdictions.[96] The latter could be more harmful, because the CBD and the NP lack positive and negative incentives for ABS compliance. For Tved, this is why ABS has become a voluntary system.[97]

[90] Brendan Tobin, 'Now you see it now you don't: The rise and fall of customary law in the IGC' (ch 10) in Daniel F. Robinson, Ahmed Abdel-Latif and Pedro Roffe (eds) *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge, London, New York, 2017), 328.
[91] Margaret Raven, 'Rethinking the Public Domain: A Challenge for Knowledge-Sharing Societies in the Information Age' (2005) 2(2) Work in Progress 23.
[92] Biber-Klemm and others (n 66) 216.
[93] Okediji (n 89) 13.
[94] Brendan Tobin, 'The search for an interim solution' in Kathy Whimp and Mark Busse (eds) Protection of intellectual, biological & cultural property in Papua New Guinea (ANU Press, 2013) 170.
[95] For example, Tobin notes that the draft European Union legislation to implement the Protocol published in 2012, adopted a very narrow approach to the identification of TK; Brendan Tobin, 'Bridging the Nagoya Compliance Gap: the fundamental role of customary law in protecting of indigenous peoples' resource and knowledge rights' (2013) 9(2) Law Environment and Development Journal 142, 148.
[96] See for example: Linda Wallbott, Franziska Wolff and Justyna Pożarowska, 'The Negotiations of the Nagoya Protocol: issues, coalitions and process' in Sebastian Oberthür and G. Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, New York, 2014) 39; Bagley (n 71) 223; Dutfield (n 16) 285.
[97] Tvedt (n 21) 160.

Despite the acknowledgement of the problems caused by bilateralism and the national approach, the difficulty of finding a single ABS norm that fits all national circumstances has also been recognised.[98]

1.3 Proposals to achieve benefit-sharing

Given the difficulties experienced by countries in the implementation of ABS, some proposals to address the problems identified have been raised. These are described below and later analysed in Chapter 7.

1.3.1 Defensive measures

Creation of databases of GR and TK has frequently been suggested as a complementary measure to achieve compliance with ABS obligations.[99] Nonetheless, as Robinson and Chiarolla state, there is no agreement on this issue. For example, within the IGC of WIPO, many delegates have supported the use of databases, contracts and codes of conduct for regulating activities (research and development, ethnobotanical fieldwork, archaeological activities, museum curation, and other related work), while others have expressed concern that these might not be sufficient to prevent erroneous patents, and have argued for a legal text for a patent disclosure of origin requirement.[100] Regarding the latter, Bagley considers that reaching agreement on a binding instrument creating a disclosure obligation for patent applicants is difficult to achieve. Instead, she proposes developing a binding instrument that reaches a middle ground, providing both floors and ceilings for disclosure requirement, through the mechanism of a formal requirement.[101]

Despite the apparent agreement on the use of defensive measures as a resource for patent examiners, for Okediji, using GR, TK and traditional cultural expressions to deny entitlement claims effectively transforms these resources in common resources and justifies anyone's access and use of them.[102] For this reason, she thinks that defensive protection measures are unlikely to significantly enhance the public domain or result in better patentability criteria; the latter because there is room for the examiner's discretion and judgement in the concession of patent rights, where limited information is only one of their constraints.[103] For her, defensive protection offers no meaningful defence against the unjust

[98] Proceedings report for the Centre for International Sustainable Development Law's (CISDL) Biodiversity Law and Governance Day (BLGD) 2018 at CBD CoP14 in Sharm El-Sheikh. Technical Report - May 2019, 8-9.
[99] See for example: Sánchez and others (n 36) 273-278; Ruiz (n 37) 129.
[100] Daniel F. Robinson and Claudio Chiarolla, 'The role of databases, contracts and codes of conduct' (ch 6) in Daniel F. Robinson, Ahmed Abdel-Latif and Pedro Roffe (eds) *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge, London, New York, 2017), 117.
[101] Bagley (n 71) 99.
[102] Okediji (n 86) 153.
[103] ibid, 156.

appropriation of TK and it confers no certain value-added dimension to the operation of the patent system.[104]

1.3.2 A trade secret based approach

Because TK is an adaptative response to biodiversity, many ILCs may possess the same or similar confidential or secret TK, i.e., knowledge that is maintained as confidential by one ILC, even though such knowledge is common to other ILCs at the same time. For these cases, Ruiz proposes a coordinated action among all communities involved for the implementation of a trade secret-based approach to ensure that TK is guarded and maintained undisclosed.[105] For its application, it would also need to incorporate an unfair competition framework and consider TK as a trade secret, provide tools to support registration of confidential TK and ensure its use only for defensive purposes, and to carry out actions towards developing the ILCs' capacity to negotiate the conditions upon which this TK would be shared and used.[106] Among all the proposals, this could be the most difficult to implement because of the level of sophistication of capacity building that may be required from ILCs and countries.

1.3.3 Customary law

Customary law has a key role to play in determining the existence or otherwise of ILC rights over GR and TK. This is why, for Tobin and Taylor, international protection of TK can be achieved through customary law,[107] including TK in the public domain.[108]

For securing recognition of customary law in foreign jurisdictions, Tobin proposes: (i) the bringing together of international customary law, human rights law, and the NP for the application of the due diligence standard to ensure that there has been compliance with their customary law and decision making process,[109] and (ii) the establishment of a verification system to certify compliance, with PIC based on customary law and overseen by an international body representing ILCs or an ombudsman, which would have links and be supported by the United Nations Permanent Forum on Indigenous Issues.[110] Concerning the process, Dutfield considers that customary law should be applied in the first instance,[111] while

[104] ibid
[105] Ruiz (n 37) 128-129.
[106] ibid, 129.
[107] Brendan Tobin and Emily Taylor, 'Across the Great Divide: A case study of complementarity and conflict between customary law and TK protection legislation in Peru' Initiative for the Prevention of Biopiracy. Research Documents. Year. IV No. 11, May 2009, Sociedad Peruana de Derecho Ambiental 16, 56.
[108] Brendan Tobin, 'The search for an interim solution' in Kathy Whimp and Mark Busse (eds) Protection of intellectual, biological & cultural property in Papua New Guinea (ANU Press, 2013) 171; Brendan Tobin, *The Role of Customary Law in Access and Benefit-sharing and Traditional Knowledge Governance: Perspectives from Andean and Pacific Island Countries* (United Nations University, WIPO, 2008) 7, 34, 41.
[109] Tobin (n 12) 156.
[110] ibid, 157.
[111] Dutfield (n 16) 287.

for Combe and Tobin, customary law should be incorporated as a third source of regulatory norms.[112]

However, for Borrows, Cornell and Muvangua, and Tobin, there seem to be 'a growing resistance by some developed nations, in particular ex-colonial powers and settler states, to the resurgence of the status of customary law under constitutional and international human rights.'[113] It could be accepted that some developing countries could show some resistance in accepting customary law as it may conflict with their own national laws and policies. Tobin adds that the application of customary law raises many practical and legal issues, where the greatest question facing the judiciary and arbitrators will be whether and to what extent they can and should adopt a flexible approach to the application of customary law principles.[114]

1.3.4 Domaine public payant, biocultural or community protocols, and cultural objection

Under the assumption that TK disclosed in publications, available in documents, or simply widely distributed is in the public domain, Ruiz proposes that three limitations on its use can be imposed. First, defensive protection, namely, registration to support the prevention of misappropriation. Second, the application of the domaine public payant in a compensatory context; and, third, biocultural community protocols to provide *ex ante* guidance on to what to expect if projects and activities are developed in the lands of ILCs. In his view, publications disclosing TK should serve to recognise the rights of its holders.[115]

Cultural objection or 'moratoria' is a proposal to safeguard TK made by some indigenous leaders, such as Lorenzo Muelas (a former Colombian senator). In short, it consists of opposing TK utilisation, and even PIC, based on cultural reasons. It is argued that ILCs have limited capacities to safeguard their cultural heritage and to control TK utilisation once access is granted. Consequently, due to the fear of possible negative impacts that access to TK could have on their culture, they have decided not to grant such access until there is a clear understanding of how their traditional lifestyles could be affected, and they have been provided with appropriate tools for the protection of TK.[116]

[112] R. Combe, 'The recognition of indigenous peoples' and community traditional knowledge in international law' (2001) 14 St. Thomas Law Review 275-285; Brendan Tobin, *Indigenous Peoples, Customary Law and Human Rights: Why Living Law Matters* (Routledge, Abindgon, 2014); Brendan Tobin, 'Traditional Knowledge sovereignty: The fundamental role of customary law in the protection of traditional knowledge' in M. Rimmer (ed) *Intellectual Property: A Handbook of Contemporary Research*, (Edward Elgar, Cheltenham, 2015) in Dutfield (n 16) 287.

[113] J. Borrows, *Recovering Canada: The resurgence of Indigenous Law* (University of Toronto Press, Toronto, 2002); D. Cornell and N. Mavangua, *Ubuntu and the Law: African Ideals and Postapartheid Jurisprudence* (Fordham University Press, New York, 2012); B. Tobin, *Indigenous Peoples, Customary Law and Human Rights – Why Living Law Matters* (Routledge, London, 2014) in Tobin (n 51) 297.

[114] Tobin (n 12) 150.

[115] Ruiz (n 37) 129-130.

[116] Florelia Vallejo Trujillo, *La Protección del Conocimiento Tradicional en Colombia* (Universidad Nacional de Colombia, Bogotá, 2010) 64.

1.3.5 National/regional laws

For Oberthür and Rosendal, as well as Tvedt, one of the causes of deficiencies in the implementation and enforcement of ABS could be found in the fact that user countries fail to effectively incorporate benefit-sharing requirements into their national legal systems. They propose: (i) the creation of an obligation for user countries to ensure that an opportunity to seek resources is available under their legal systems in cases of disputes arising from MATs; (ii) implementation of effective measures regarding access to justice; and, (iii) mutual recognition and enforcement of foreign judgements and arbitral awards.[117] In a similar vein, Tvedt highlights the fact that failure to enact compatible legislation in user and provider countries makes it difficult to enforce ABS in courts or through other judicial means. In his view, compliance can be achieved by using the international customary law because this would lead to state responsibility.[118] For his part, Isozaki considers that achieving fairness and equity in national laws should be pursued through the application of the principle of 'mutual benefit,' so that benefit-sharing will only apply when a company receives any tangible benefit.[119] Tvedt does see the need for strong sanctions to motivate user countries to adhere to the rules of providing countries,[120] and considers that standardization of ABS national laws can be made functional under the ABS system at the international level[121]. He is also in favour of a reporting system, although acknowledging that the ABSCH has not fully achieved its objective in this respect.[122] Isozaki proposes the creation of a network of national or local ABS offices, each of which should incorporate a clearing-house to assist the Parties in MATs negotiations and to monitor the status of compliance of MATs with domestic law.[123] Delivering MATs have positive effects on ABS compliance because, as noted by Tvedt, ABS obligations can only be enforced before a court when a MAT exists.[124]

For their part, Morgera, Buck, and Tsioumani assert that ABS implementation can only succeed 'on the basis of incentives, trust and pragmatism, allowing for a certain degree of experimentation on the ground and the possibility to complement international obligations with bottom-up approaches or incentives by indigenous and local communities, the research community, or the private sector.'[125]

[117] Oberthür and Kristin Rosendal (n 13) 6; Tvedt (n 21) 158-159.
[118] Tvedt (n 21) 158, 161-163.
[119] Hiroji Isozaki, 'Enforcement of ABS Agreements in User States' (ch 23) in Evanson Kamau, and Gerd Winter (eds), *Genetic Resources, Traditional Knowledge and the Law. Solutions for Access & Benefit Sharing* (Earthscan, 2009) 450.
[120] Tvedt (n 21) 165.
[121] ibid, 166.
[122] ibid, 174.
[123] Hiroji Isozaki, 'Enforcement of ABS Agreements in User States' (ch 23) in Evanson Kamau, and Gerd Winter (eds), *Genetic Resources, Traditional Knowledge and the Law. Solutions for Access & Benefit Sharing* (Earthscan, 2009) 450-451.
[124] Tvedt (n 21), 172.
[125] Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges* (Legal Studies on Access and Benefit-sharing, v. 1, BRILL Nijhoff 2012), 507.

For Fisher, a complex and more variegated system of norms, consisting of three parallel provisions that serve as a defence to a claim of patent, trademark, and copyright infringements is a better option than a harmonised global regime. The main idea is to preclude enforcement of IPRs in instances where those rights derive from unauthorised access and use of GR and TK.[126] Similarly, Mgboji suggests that it would be 'practically impossible for weak states to create a new global legal mechanism for the protection of plants and TK'. For this reason, he considers their best option would be the creation of a regional patent system that reflects their particular concerns, priorities and values.[127]

1.3.6 Courts

Godt suggests that ABS reclamations can be raised in Europe based upon either the law of contracts or torts,[128] and proposes civil suits for damages based on 'immaterial rights sui generis' as another route to be explored.[129] She also considers that reparation of damages can be established upon the economic value of the material good as taxed and/or the equivalent to the license fee payable for the infringement of an immaterial good.[130] Similarly, Isozaki considers, in the case of non-compliance with MATs, that a lawsuit could be instituted at a user's national court, and recommends the use of arbitration tribunals for disagreements or non-compliance with MATs.[131] For Chiarolla, compliance with MATs can be achieved through private international law,[132] while for Tobin, the burden of enforcing ILC rights is likely to fall on national or regional human rights courts, such as the Inter-American Court of Human Rights, and alternative dispute resolution mechanisms.[133] Thus, he proposes the creation of a jurisdiction in the country of origin of ILCs to protect TK in cases of infringement in another country. This is because 'courts often cannot hear cases against foreigners who have no connection with the jurisdiction, but if the act of infringement has a subject matter connection to the place where the court sits some courts will take jurisdiction.'[134]

[126] William Fisher, 'Two Thoughts About Traditional Knowledge' (2007) 70 Law and Contemporary Problems 131–134 in Okediji (n 85) 161-162.
[127] Ikechi Mgboji, *Global Biopiracy : Patents, Plants, and Indigenous Knowledge* (UBC Press, 2005) 195.
[128] Christine Godt, 'Enforcement of Benefit-Sharing Duties in User Countries' (Chapter 22) in Evanson Kamau, and Gerd Winter (eds), *Genetic Resources, Traditional Knowledge and the Law. Solutions for Access & Benefit Sharing* (Earthscan, 2009), 432.
[129] ibid
[130] ibid
[131] Isozaki (n 123) 441.
[132] Claudio Chiarolla, 'The Role of Private International Law under the Nagoya Protocol' (ch 4) in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges* (Legal Studies on Access and Benefit-sharing, v. 1, BRILL Nijhoff 2012), 424.
[133] Tobin (n 12) 150.
[134] Tobin (n 90) 328.

1.3.7 International instruments or existing institutions

Young suggests modelling particular elements of ABS on elements of other international instruments or trying to incorporate the operation of particular elements of ABS into the work already undertaken by existing institutions. For her, the 'comparability' and 'functionality' of the systems will determine whether another framework or regime would provide a useful model for ABS. In her approach, 'comparability' means having a similar general structure, and 'functionality' involves similar underlying factors that motivate effectiveness. She notes that the most common attempts to use such shortcuts have arisen with regard to monitoring aspects.[135] Similarly, Coolsaet, Dedeurwaerdere, and Pitseys propose applying other mechanisms from different sectors to ABS, including integrating ABS obligations within patent and IP schemes at national and international levels, using the Convention on International Trade in Endangered Species (CITES) and customs control entities, as well as the creation of certification systems.[136] Another approach, from Dedeurwaerdere and others, suggests the implementation of a full-fledged intergovernmental organisation based on a binding international treaty, like the MLS of FAO; i.e. a purely science-driven non-governmental organisation building upon existing institutions like the World Federation for Culture Collections (WFCC) or the International Union of Microbial Sciences; or a contractual framework between willing governments to establish a common position as adopted, for example, by the International Rice Genome Sequencing Project.[137] For Dedeurwaerdere and others, the gap between the formal institutional arrangements of the system and the goals of the scientific community is one of the leading issues to be addressed.[138] Regarding the level of internationalisation of the instrument that would operate, Isozaki considers that regional rather than national centres would be more likely to achieve control over common resources.[139]

For their part, Halewood and others claim that adopting an approach such as that proposed by Dedeurwaerdere and others may have the following negative impacts: (i) limited scope to plant GR; (ii) insufficient policy reinforcement, which allows contributors and non-contributors to the MLS to benefit equally from the system; and, (iii) a mandatory financial benefit-sharing provision which falls somewhere between multilateralism and bilateralism, undermining the participation of some actors in the MLS.[140]

[135] Tomme Rosanne Young, 'An International Cooperation Perspective on the Implementation of the Nagoya Protocol' (ch 5) in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges* (Legal Studies on Access and Benefit-sharing, v. 1, BRILL Nijhoff 2012), 464. 465.

[136] Brendan Coolsaet, Tom Dedeurwaerdere, John Pitseys, 'The Challenges for Implementing the Nagoya Protocol in a Multi-Level Governance Context: Lessons from the Belgian Case' (2013) 2(4) Resources 555, 573-574.

[137] Dedeurwaerdere and others (n 70) 402-403.

[138] ibid 401.

[139] Isozaki (n 123) 451.

[140] Michael Halewood, Isabel López Noriega and Selim Louafi (eds), 'Crop Genetic Resources as a Global Commons. Challenges in International Law and Governance' (Earthscan, 2012) in Dedeurwaerdere and others (n 70) 411.

1.3.8 Development of new agreements

For Cabrera and López, the issues on ABS operativity could be best solved by the achievement of new international agreements.[141] Similarly, Dedeurwaerdere and others seek to build bilateral or multilateral framework agreements between willing governments as the most feasible short-term solution.[142] As an example, they point to the International Rice Genome Consortium, a consortium established by a collaborative agreement between research organisations, the private sector, and the government.[143] Young also believes that bilateral negotiations offer the best hope for developing countries in addressing ABS implementation. However, she draws attention to the fact that this approach is potentially beneficial to developed countries seeking to support users in their jurisdictions.[144]

1.4 Proposals for the implementation of a global multilateral benefit-sharing mechanism (GMBSM)

Article 10 of the NP proposes the creation of a global multilateral benefit-sharing mechanism (GMBSM) for GR and TK in transboundary situations or where it is not possible to grant or obtain PIC. Benefits derived from this mechanism are expected to be used to support the conservation and sustainable use of biodiversity on a global scale. Although this norm does not mention the establishment of a fund as the mechanism for the distribution of benefits, most of the views expressed in regard to the way such a GMBSM should be designed include the implementation of an international fund. Those views also tend to modify (usually to extend) the scope of Article 10. This tendency can be partly explained because these proposals, in addition to seeking the implementation of a GMBSM, usually try to solve some of the weaknesses identified in the ABS design. For example, Ruiz proposes the application of this mechanism for all GR and TK because, despite the fact that they are intangibles, policies drafted and implemented are identical with those for tangibles.[145] Vogel and others appear to agree with the idea of a global solution for benefit-sharing, considering this as a way to remove the negative effects of the bilateral approach of ABS. In their view, the bilateral approach can never be fair or equitable, as the competition among providers would cause a fall in prices of accessing GR and deny any benefit to all parties but one.[146] The previous and more examples of the proposed mechanisms to implement the GMBSM of the NP are presented below.

[141] Jorge Cabrera Medaglia and Cristian López Silva, 'Addressing the Problems of Access: Protecting sources, while giving users certainty' (IUCN Environmental Policy and Law, Paper No. 67/1 2007), 65.
[142] Dedeurwaerdere and others (n 70) 420-421.
[143] ibid 410.
[144] Young (n 135) 505.
[145] Ruiz (n 20) 36.
[146] Vogel, Ruiz, and Angerer (n 16)

1.4.1 Funds

The creation of common funds as a mechanism that could realise the distribution of benefits has been proposed often.[147] For Parry, benefits would be paid directly into a superfund, that would ideally be administrated by a global regulatory agency such as the Global Environment Facility, to which countries and ILCs might apply with proposals for development and conservation projects.[148] For Vogel and others, benefits derived from the use of GR would be directed towards a global fund to be distributed among all countries of origin, proportional to their habitat.[149] The International Barcode of Life (iBOL) could facilitate that determination.[150] This form of benefit-sharing would not be applied, however, for rare commercial success, and cases where the origin of the resource is ubiquitous (e.g., many microorganisms). In the first scenario, the best estimate of boundaries based on the current state of science would be applied. In the second, the royalties collected 'should defray the fixed costs of the infrastructure which drives the system.'[151] This final sentence seems to imply the exclusion of some resources to pay the operational costs of the system. While guaranteeing the sustainability and operability of any system is logical and necessary, one would think that countries would not readily agree to this type of proposal because it could limit the benefits they can receive. These authors also explain that MATs would be binding only for the natural information (GR) that is endemic to the provider, so that, in any other case, the user would have to remit royalties to the global fund.[152] Smith places doubts on the proposal by Vogel and others because the practicality of benefit-sharing based on the percentage of habitats or ecosystems of a country has not been scientifically demonstrated.[153] On this subject, Tangham Galea stresses that Africa would require substantial capacity building and technology transfer to make this system work,[154] and Young and Minnis suggest that the lack of clarity in the determination of the causes triggering ABS obligations could impede the global regime functionality.[155]

As discussions have advanced, new resources other than GR, such as TK, synthetic biology, databases of GR information and TK, and continued uses of GR collected before the

[147] See for example: Enrique Sánchez and others (n 36) 276; Peter Drahos, 'Indigenous Knowledge, Intellectual Property and Biopiracy: Is a global bio-collecting society the answer?' (2000) 22(6) European Intellectual Property Review 245, 246.

[148] Bronwyn Parry, *Trading the Genome : Investigating the Commodification of Bio-Information* (Columbia University Press, 2004) 262.

[149] Vogel and others, (n 1) 379.

[150] ibid, 383.

[151] ibid, 384.

[152] Vogel, Ruiz, and Angerer (n 16) 3.

[153] ibid, 384.

[154] ibid, 385-386.

[155] T.R. Young, A. Minnis (eds), K. Angerer, L. Benjamin, E.C. Kamau, G. Dutfield, C.H.C. Lyal, E. Mawal, S. Peña Moreno, M. Ruiz Muller, T.T. Huong Trang and J.H. Vogel (2015) 'Submission of views in preparation for the Expert Meeting on the need and modalities of a Global Multilateral Benefit-sharing Mechanism of the Nagoya Protocol' Collective submission of the IUCN Joint SSC-WCEL Global Specialist Group on ABS, Genetic Resources and Related Issues (ABSSG) in Vogel and others (n 1) 388.

CBD have been considered for their inclusion in fund regulations for benefit-sharing. For example, in the case of shared and widely distributed TK, Ruiz proposes the creation of a fund[156], and Vogel and others recommend the use of funds as a mechanism to achieve benefit-sharing due to factors such as: (i) control of exclusive rights over this type of TK is impossible to exercise; (ii) some ILCs could be excluded from the benefits; (iii) PIC might be impossible to obtain where there is no defined right holder; and, iv) tensions may be created among and between the ILCs participating in the process of negotiation.[157] Regarding synthetic biology, Bagley suggests assimilating the uses of GR information from accessible databases in a transboundary situation or in a situation where it is not feasible to obtain PIC, thus enabling collection and distribution of the benefits derived from their use through a common fund.[158] Parry advocates for the inclusion of databases and continued uses.[159]

The MLS of FAO implements a global fund for the distribution of benefits of plant GR used under this system. For that reason, some academics have looked at the experience gained through the implementation of this fund to make recommendations for the GMBSM. For example, Chege Kamau considers that the MLS: (i) creates space for participation of developed and developing countries because, allegedly, developing countries receive technology from developed countries;[160] (ii) strengthens the obligation of users to share benefits with providers; (iii) establishes a system of monitoring the downstream movement of materials by obliging the recipients to report each transfer downstream to the Governing Body; (iv) establishes a fund with benefit-collection and benefit-distribution functions; (v) harmonises the calculation of payments for commercialisation, and centralises revisions and variations to the level of payment under the sole discretion of the Governing Body; (vi) bases the criteria for benefit-sharing not on the source country but on the need for conservation and sustainable use;[161] and, (vii) facilitates free access to GR for the purposes of research that is beneficial to conservation and sustainable use.[162] Kamau also sees the financial, technical and institutional incapacity of many developing countries, the imbalanced rights and obligations, and the impact of IPRs as the main causes affecting the optimum implementation of the MLS.[163] On the contrary, for Bagley, the MLS 'has not been a success to-date' given that 'virtually all contributions to the fund have come from countries, not commercial enterprises, and the fund has collected millions of dollars less than had been forecast.'[164]

[156] Ruiz (37) 122, 125.
[157] Joseph Henry Vogel and Manuel Ruiz, 'The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access and Benefit Sharing' (2011) 7(1) Law, Environment and Development Journal 52, 65.
[158] Bagley (n 71) 229.
[159] Parry (n 148) 262.
[160] Evanson Chege Kamau, 'The multilateral system of the International Treaty on Plant Genetic Resources for Food and Agriculture: Lessons and room for further development' (ch 17) in Evanson Chege Kamau and Gerd Winter (eds) *Common Pools of Genetic Resources: Equity and innovation in international biodiversity law* (Earthscan, London and New York, 2013) 343-344.
[161] ibid, 344.
[162] ibid, 345.
[163] ibid, 346.
[164] Bagley (n 71) 229-230.

1.4.2 A cartel of provider countries

Vogel proposes the creation of a cartel of provider countries which would distribute the benefits derived from the use of GR. For the cartel's function, access to GR should remain free under a scheme of 'bounded openness' (explained later in this chapter).[165] This idea of a cartel is close to the 'collusive oligopoly' or 'trust' or 'cartel' understood by Samuelson and Nordhaus as 'an organisation of independent firms, producing similar products, that work together to raise prices and restrict output' that brings, as a result, the ability for companies to agree to charge the same price (which maximises their joint profits) and to share the market.[166] Based on economic theories, Vogel understands that because the object of interest for Research and Development (R&D) is the natural information and not the vehicle (GR), competition among provider countries will reduce the price of the genetic material to the cost of access, where the CBD failure to generate benefits from bilateral bioprospecting agreements lies.[167] For Vogel, Ruiz, and Angerer, this cartel could eliminate competition among providers, allowing benefit-sharing.[168]

1.4.3 Rents

For Vogel and others, payment of rents on the use of GR is justified by the intangible nature of GR as information. They see this as the same justification for rents under IPRs, which could be achieved through the creation of a 'cartel of provider countries' (previously explained) and would establish rents that would be directed toward a common fund.[169] To secure compliance, a cost for non-disclosure of the use of natural information in patent applications, greater than the benefit of non-compliance, should be established. A sharing of benefits would only be required for commercially successful patents,[170] no PIC or MATs would be needed, and GR *ex-situ* would be covered under this system, as the royalties would be standardized across Parties according to a negotiated matrix of utilizations that would apply, even in the absence of measures in a Party to implement ABS.[171] Eleven steps were designed for the application of this modality,[172] where encouragement of non-member countries to adhere to the CBD and

[165] Joseph Henry Vogel, 'Case Study 6: Bioprospecting' in WHITE PAPER final report The Successful Use of Economic Instruments to Foster Sustainable Use of Biodiversity: Six Case Studies from Latin America and the Caribbean, Commissioned by the Biodiversity Support Program on behalf of the Inter-American Commission on Biodiversity and Sustainable Development In preparation for the Summit of the Americas on Sustainable Development, Santa Cruz de la Sierra, Bolivia December 6-8, 1996; available in <https://www.cbd.int/doc/case-studies/abs/cs-abs- cartel.pdf> accessed in 03.02.2019

[166] Paul A Samuelson and William D Nordhaus, Economics (Nineteen Edition, McGraw-Hill/Irwin, New York, 2010) 190.

[167] Vogel (n 165) 37.

[168] Vogel, Ruiz, and Angerer (n 16) 1.

[169] Vogel and others (n 1) 379.

[170] Vogel, Ruiz, and Angerer (n 16) 3.

[171] ibid, 4-6.

[172] Vogel, Ruiz, and Angerer (n 16) 2.

the NP could be achieved by levying a royalty on biotechnology imports to Parties which derive from transboundary resources (for these authors, GR are transboundary resources when accepted that they are natural information) in a non-Party.[173] This last part of the proposal seems a logical and feasible solution that not only could achieve the adherence of countries to the CBD and the NP, but also could constitute the base for an ABS collecting system similar to the collective copyright management societies, though only if the countries agree on it as a mechanism for benefit-sharing.

Concerning the way a cartel of provider countries should be implemented, Ruiz explains that in Vogel's view, countries and ILCs which could have supplied a GR or a 'secret' TK would share in a set royalty of 15%, according to the habitat size or, in the case of secret knowledge, proportional to the number of communities that register the same knowledge.[174] Similarly, for Parry, the best option for benefit-sharing could be reaching a voluntary global agreement where the pharmaceutical industry could share between 3 and 5% of their profit ration to (i) all products in use regardless of whether or not they were accessed before or after the CBD; and (ii) to genetic-sequence and TK databases.[175]

Criticising Vogel's proposal, Roca argues that it appears to suggest GR liberalisation through the establishment of a global uniform rate for commercialised patents using GR. He considers that Vogel's error is in the assertion that neo-classical theory is characteristic of biodiversity analysis as a public good, when according to the economic literature, this type of analysis applies to private goods.[176] In Roca's opinion, there is no way to determine the economic value of the natural information used in the production of private goods, because the market works better at the end of the productive chain rather than at the beginning. Thus, the application of political-administrative rules, such as the regulation and market policy doctrine, would be preferable, although in his view the use of MATs could also be a possibility.[177] Roca sees Vogel's proposal as the privatisation of GR for the purpose of conservation. He concludes that if this is the aim, biodiversity should not be privatised, and instead of the tax payments proposed, limits to deforestation together with sanctions and class actions should be implemented.[178]

Another important point to note is that, for his proposal, Vogel uses as an example the experience of the oil industries. This is critical because every time a company wishes to do business in the oil sector, it must go to the country of origin of the resource to extract it *in-situ*. In theory, this means that the country of origin can control the use of its resources and is able to create/be a part of a cartel of provider countries for establishing a standardised international

[173] ibid, p. 3.
[174] Ruiz (n 20) 37.
[175] Parry (n 16) 260-262.
[176] Santiago Roca, 'El Patentamiento de Genes a Cambio de la Formación de un Cartel de Países Proveedores de Información Genética: ¿Una Retórica Falaz y Sesgada?' in Santiago Roca (ed) *Biodiversidad y Propiedad Intelectual en Disputa. Situación, propuestas y políticas públicas* (ESAN Ediciones, 2016) 97.
[177] ibid, 105.
[178] ibid, 106.

price for the extraction. However, given that there is no need to access GR *in-situ* every time resources are used, the analogy may not be appropriate.

Roca also argues that for the establishment of a rent, a new agreement must be achieved on sensitive issues such as the concept of GR as natural information and a matrix of utilization on which benefits would be distributed.[179] In the light of experience in the processes of negotiation of the CBD and the NP, Roca's warning seems entirely valid, as it appears that achieving an agreement that allows different implementation of the designed ABS system under the CBD is not possible—at least for now. As some authors have noted, countries may not agree on expanding the scope or operability of the ABS system in a way that would threaten their existent rights, which has nothing to do with the unfavourable conditions that could exist during those negotiations.[180]

Moreover, the proposal of Vogel and others appears to be focused only on the monetary benefits. This is because it does not take into account the non-monetary benefits such as the transfer of technology or the sharing of scientific information, which may be of interest to provider countries. Adding to this, in Ripley's opinion, a flat royalty rate would leave aside considerations about different industry-cost structures or market prices and could influence companies' decisions on whether to use GR in R&D.[181] Although Vogel and others seem to be well aware of the difficulties in achieving agreement on a system different than the one enshrined in the CBD and the NP, for them, this task needs to be done.[182]

Finally, it should be noted that Vogel's proposal does not include the whole spectrum of TK, as it excludes everything which is not secret, which, according to Ruiz, may comprise the largest portion of TK.[183] Also, benefit-sharing with ILCs seems to be subjected to a register of TK that in many cases may not exist. These aspects could be problematic because ILCs do not always have these systems in place, and because of the issue of excluding widely-disseminated TK from ABS, as previously explained.

1.4.4 Bounded openness

For Vogel and others, under the criteria of efficiency and equity, 'bounded openness' is the optimal modality for transboundary situations.[184] This term is defined by the Peruvian Society of Environmental Law as 'legal enclosures which default to, yet depart from, res nullius

[179] ibid, 97-106.
[180] See for example: Sarah Winands-Kalkuhl, Karin Holm-Müller, 'Bilateral vs multilateral? On the economics and politics of a global mechanism for genetic resource use' (2015) 7(4) Journal of Natural Resources Policy Research 305-322 in Vogel and others (n 1) 382; T.R. Young, A. Minnis (eds), K. Angerer, L. Benjamin, E.C. Kamau, G. Dutfield, C.H.C. Lyal, E. Mawal, S. Peña Moreno, M. Ruiz Muller, T.T. Huong Trang and J.H. Vogel (2015) 'Submission of views in preparation for the Expert Meeting on the need and modalities of a Global Multilateral Benefit-sharing Mechanism of the Nagoya Protocol' Collective submission of the IUCN Joint SSC-WCEL Global Specialist Group on ABS, Genetic Resources and Related Issues (ABSSG) in Vogel and others (n 1) 388.
[181] Vogel and others (n 1) 386.
[182] Vogel and others (n 1) 384-385.
[183] Ruiz (n 37) 122.
[184] Vogel and others (n 1) 377.

[property of no one], to the extent that the departures enhance efficiency and equity, which must be balanced when in conflict.'[185] Under this idea, GR will be freely accessible, a cartel of provider countries would control the prices for its access, and the benefits would be collected through a common fund.[186] Given this, bounded openness could be seen as a form of common pool of GR. As already mentioned, Roca opposes GR liberalisation,[187] while du Plessis sees bounded openness as fairly unassailable and considers it as a complementary option for the bilateral ABS system.[188]

1.4.5 Common pools

For Winter, common pools of GR and TK could alleviate some ABS deficiencies. In this case, the common pool comprises GR and TK provided by resource holders to a group of people for common use. Resource holders cooperate in the preservation of their resources, and providers and users enter into cooperative R&D, enriching their capacities and sharing the monetary and non-monetary benefits produced. Under this scheme, providers become users when participating in R&D processes, and users become providers by feeding their R&D results into the pool. Thus, (i) equity can be achieved between providers having the same GR and TK and between providers and users; (ii) R&D is enabled; and, (iii) resources and incentives to preserve biodiversity are provided.[189]

Although common pools have long existed as in the case of seed exchange systems, networks of botanical and zoological gardens, network of microbial collections and biological databanks, Winter is conscious that free use of resources from the pool may prevent participants from supplying their GR, TK, and results (knowledge and money) to the commons.[190] In his view, ABS caused a negative impact on this type of common pool 'because resource holders are affirmed as proprietors and encouraged to make individual use of their rights.'[191] For him, this 'dilemma' could be solved by placing a duty on users to feed their own material, knowledge, and gain into the pool, and by enhancing the participatory rights and opportunities of providers within the pool.[192] He finds the positive effects of pools on R&D sufficient enough to defend their implementation against ABS claims of individual providers.[193] Similarly, Stoll claims that, because the Convention on the Law of the Sea declared certain parts

[185] Peruvian Society of Environmental Law (SPDA) 'Submitted view for the Updated report and synthesis of views in response to paragraph 7(b) of Decision XII/24; and Report of the Meeting of the Ad Hoc Technical Expert Group on Synthetic Biology' (2016) 2 in Vogel and others (n 1) 378.
[186] ibid, 379.
[187] Roca (176) 97-106.
[188] Vogel and others (n 1) 385.
[189] Gerd Winter, 'Common pools of genetic resources and related traditional and modern knowledge: An overview' (ch 1) in Evanson Chege Kamau and Gerd Winter (eds) *Common Pools of Genetic Resources: Equity and innovation in international biodiversity law* (Earthscan, London and New York, 2013) 3-4.
[190] ibid, 4.
[191] ibid, 5.
[192] ibid
[193] ibid

of the deep seabed and its mineral resources to be the common heritage of mankind and provided a number of mechanisms to enable developing countries to participate in mining activities and benefit from its commercial results, benefit-sharing can be achieved by either assigning a sovereign entitlement to a resource or by creating a common good based on the concept of a common heritage of mankind.[194] However, for Mgbeoji, this concept is not applicable to plant GR and seems to oppose the idea of a global commons of GR that is freely available to all mankind.[195]

For Winter, there are three ways to offer provider state incentives for waiving their rights into common pools: (i) introducing conditions for the use of data, requiring that any commercial use must first be agreed upon with the provider state; (ii) requiring the database organisation to ask for disclosure of the country of origin of the sample from which the data were derived; and, (iii) enabling the tracking back and forth of R&D processes, unique and interchangeable identifiers of genes and tools to connect information would have to be developed.[196] Noticeably, proposals involving payments for commercial use and disclosure obligations are not new. It is relevant, therefore, to ask what has not worked well in the ABS system for common pools.

Regarding benefit-sharing, Winter proposes that databases could be responsible for supervising use, collecting and redistributing the shares' monetary benefits; or that a system which he calls the 'biodiversity charge' could be created. It seems that this proposal consists of a tax on sales of products based on GR to be collected through a single or many funds, as Vogel and others proposed.[197]

1.4.6 A global bio-collecting society

On the grounds of copyright-collecting societies, Drahos proposes the creation of a global bio-collecting society consisting of a private organisation to distribute the benefits derived from TK utilisation.[198] The differences between copyright-collecting societies and his proposal are: (i) rather than having many collecting societies at the national level, there will be only one global bio-collecting society; (ii) the purpose of the bio-collecting society will be the protection of TK; therefore, membership of the society in itself constitutes an acceptance that ILCs property rights will be respected; and, (iii) fund resources would come from the World Bank.[199] Participation of companies and ILCs in the global bio-collecting society would be encouraged through the provision of ABS-related services. For companies it will offer freedom

[194] Peter-Tobias Stoll, 'ABS, justice, pools and the Nagoya Protocol' (ch 15) in Evanson Chege Kamau and Gerd Winter (eds) *Common Pools of Genetic Resources: Equity and innovation in international biodiversity law* (Earthscan, London and New York, 2013) 306.
[195] Ikechi Mgboji, 'Beyond Rhetoric: State Sovereignty, Common Concern, and the Inapplicability of the Common Heritage Concept to Plant Genetic Resources' (2003) 16 Leiden Journal of International Law 821, 823.
[196] Winter (n 147) 290-291.
[197] ibid, 291.
[198] Drahos (n 147) 247.
[199] ibid, 247-248.

of contract, low search and transaction costs, and certainty of use. For ILCs, the benefits are recognition of their property rights over TK by the user companies, a means by which they could enforce their rights (although the proposal does not mention how their rights will be enforced), monitoring the use of TK, help with the negotiation of licensing agreements, and collection and distribution of royalties.[200] The following services are proposed in addition to what has just been mentioned: (i) repository for community registers of TK; and (ii) a dispute resolution function.[201]

Although Drahos admits that functionality of this collecting society will depend largely upon its membership, he believes that it could provide order between international companies and local actors, and avoid corruption in some developing countries that could potentially affect ABS implementation.[202]

2. Hypothesis, research questions and methodology

The initial aim of this thesis was to analyse ABS to propose a feasible way in which an ABS mechanism could be designed for the distribution of benefits derived from the use of TK. However, during the research stage of this study, it was decided to present recommendations for the implementation of a single system of ABS. This avoids any potential negative effects that might result from the division of ABS into two separate processes, one for GR and one for TK, and recognises the need to link the use of TK with that of GR. With that purpose in mind, the way in which the countries have implemented ABS through national laws, the ABS system of the CBD, its further development in the NP, its relationship with other ABS systems and the IP system have been studied.

The analysis was conducted while taking into account the difficulties experienced by countries during the process of negotiation, agreement, and incorporation of ABS obligations in the texts of the CBD and the NP. Among other things, Chapters 2 and 3 suggest that new agreements, with the potential to modify the contents of the CBD and NP, could be difficult to achieve in the near future. One possible implication of this is that, as countries have shown a great deal of disagreement on different developments, some aspects contained in the proposals summarised in Chapter 1 would be difficult to implement, despite their reasonableness. To consider one example, the concept of GR has been redefined by some academics as information, to affirm that, within the ABS context, all GR are transboundary and, therefore, all benefit-sharing should be conducted through a global mechanism, as indicated in Article 10 of the NP. Although this interpretation and the proposal itself could be considered valid and reasonable, it is highly probable that the Parties to the CBD and NP would not agree to such an interpretation because, based on the records of the negotiation sessions of the NP, it appears that the countries could not agree on better definitions or conditions for the ABS

[200] ibid, 248.
[201] ibid, 247.
[202] ibid, 248-149.

system. Furthermore, from those records, it can also be inferred that the countries were aware of the limitations imposed on ABS by the contents of the CBD.[203]

Consequently, the literature review and the difficulties experienced during the negotiations of the NP suggest that the possibilities for the design of an ABS mechanism could be the result of proposals supported on: (i) theoretical approaches; (ii) practical bases; or (iii) a combination of these two.

This thesis addresses that issue from a more practical approach, suggesting that by reviewing how the countries have implemented ABS in their practice is a more feasible response to proposed recommendations for the designing of an ABS mechanism. Regarding the implementation of laws, some studies exist about the cases in which the law to be implemented has not been designed specifically for the country (i.e., the concrete situation) in which they will be applied. Particularly, the analysis made on this matter by López, de Sousa Santos, and McCann and March constitute the theoretical basis of the methodological approach of the work that has been done.

López has extensively studied the limitations in the interpretation and application of legal texts deriving from theories and general principles of law from one country to another (understood as the copy and paste of laws). He has demonstrated, for example, how the narratives and legal culture are different in Latin America (the so-called place of reception) from those in Europe (the so-called place of production), even though those narratives are based on the same legal texts, theories, and principles.[204] Despite the different approaches to legal transplants,[205] the work of López is important for this thesis because its conclusions are based on the practical consequences of legal transplants. From legal pluralism theories, de Sousa Santos suggests that a legal system designed from the existent reality is more likely to be effective, due to people's willingness to comply with rules closer to their real world.[206] For their part, McCann and March encourage examination of the way the law is used by citizens in their everyday lives as one of the most valuable forms of legal research.[207]

[203] See for example: Stefan Jungcurt and others, 'Summary of the Resumed Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 10-16 July 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 19 July 2010, vol 9, n 527); and 'Summary of the Tenth Conference of the Parties to the Convention on Biological Diversity: 18-29 October 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 1 November 2010, vol 9, n 544); Johannes Gnann and others, 'Summary of the Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 22-28 March 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 31 March 2010, vol 9, n 503).

[204] Diego López, *Teoría Impura del Derecho: Transformación de la cultura jurídica latinoamericana* (Universidad de los Andes, LEGIS, Universidad Nacional de Colombia, 2004) Chapter 1.

[205] See for example: Tran Kien, 'Can copyright law be transplanted? Vietnam's experiences with droit d'auteur, 1864-1975' (ch 22) in Paul Torremans (ed) *Research Handbook on Copyright Law* (Edward Elgar Publishing, Cheltenham, Northampton, second edition, 2017) 539-540.

[206] See for example: Boaventura de Sousa Santos, *Estado, Derecho y Luchas Sociales* (ILSA, 1991) 163-165; 'El Discurso y el Poder: ensayo sobre la sociología de la retórica jurídica' (Revista Crítica Jurídica No. 26, 2007) 78-81, 91-98.

[207] Michael McCann and Tracey March, 'El derecho y las formas cotidianas de resistencia: una evaluación sociopolítica' (ch 9) in Mauricio García Villegas (ed) *Sociología Jurídica: Teoría y sociología del derecho en Estados Unidos* (Universidad Nacional de Colombia, 2001) 306-309, 329-330.

One aspect of these theories seems to be confirmed by the low level of implementation of ABS expressed in the number of accessions of samples of biological materials through the MLS versus the number of MATs reported to the ABSCH. This indicates that it is very difficult to shape human behaviour through the implementation of laws.[208] Seemingly, one of the causes of this limited application is the lack of coherence between ABS and the realities of current institutional practice, as indicated in the literature review.[209] This being the case, it might be possible that a system regulating the way users of biodiversity and TK behave could more easily be adopted than a system which is trying to change behaviour. This is particularly true when those behaviours are rooted in common and accepted practices based on the rules of well-established systems, such as the *ex-situ* centres that are part of the CGIAR,[210] botanical gardens such as Kew,[211] and gene-banks such as the Rice Genome Consortiums of the IRRI,[212] among others.

For this reason, in this thesis, the study of the way in which the countries have designed their ABS systems will prevail over the theoretical approaches to the problem. Particular attention is given to developments within sensitive ABS issues, such as GR *ex-situ*, the public domain, and shared TK. Nonetheless, this thesis is also aware that a comprehensive study of ABS, involving its development, contents, and relationship with the legal systems to which it relates, is also indispensable to gain a better understanding of the logic and the context in which it is applied and to provide a better opportunity to find the key elements that would be required for a feasible implementation of ABS.

In view of the above, the hypothesis of this thesis is that the ABS mechanisms incorporating elements already implemented by some countries may potentially be more readily acceptable to the Parties to the CBD and the NP, as well as by the providers and users of GR and TK. A proposal developed from a purely theoretical approach can find obstacles in practice. Therefore, such a practical approach has a better possibility of success in the task to achieve benefit-sharing.

This does not mean that the existent studies and proposals on how to improve ABS have no value or are not of interest in this thesis. Those proposals are taken into account to complement the findings from the implementation of national laws on ABS, for which a

[208] As of 31 October 2016, Easy-SMTA (an online non-mandatory application that assists users in the generation of Standard Material Transfer Agreements -SMTA-) had 1,272 users with 5,985 unique recipients of material worldwide. 48,313 SMTAs were agreed with providers located in 35 countries, and the plant GR was distributed to recipients based in 175 countries. In time, these SMTAs had transferred 3.25 million accessions. For its part, as of 15 March 2018, notification of the issuance of 143 MATs has been provided to the ABSCH (see Table 3, in chapter 2).
CBD, COP-MOP, 'Update on recent developments under the International Treaty on Plant Genetic Resources for Food and Agriculture of relevance to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation' (2016) UNEP/CBD/NP/COP-MOP/2/INF/10.
[209] Dedeurwaerdere and others (n 70) 401.
[210] CGIAR is a global research partnership for a food secure future dedicated to reducing poverty, enhancing food and nutrition security, and improving natural resources. More information at: https://www.cgiar.org/research/research-centers/
[211] More information at: https://www.kew.org/
[212] More information at: https://www.irri.org/about-us/research-networks

doctrinal methodological approach was used. Nevertheless, they are considered only so far as they are compatible with the contents of the CBD and the NP. This is because, as Vogel and Ruiz have argued, there seems to be resistance to including new aspects in the discussions on ABS.[213] Additionally, with the aim of offering a more accurate approach to the technical concepts of the CBD and NP, informal chats with Professors working in the field of natural sciences were held, and literature from the life sciences, social sciences and humanities fields were consulted. Moreover, when required, the history of the discussions on ABS was taken into account and contexts are provided based on the official records of the negotiations available on the CBD webpage.

Based on the hypothesis, this thesis proposes the following research question: what are the key elements required for a feasible implementation of ABS? To answer this question, the thesis also aims to resolve the following questions:

1. In what way have the Parties to the CBD and the NP developed national laws on ABS?
2. What is the design of ABS in the CBD and the NP?
3. How should the core elements of ABS be understood?
4. In which way does the ABS system of the CBD connect with the ABS systems of the FAO and the WHO?
5. In what way does ABS relate to the IP system?

Each of these sub-questions is examined individually in each chapter of the thesis. The final conclusions, presented in Chapter 7, are based on two main ideas. First, that the current ABS rules have been made at a high international political and diplomatic level without considering the behaviour of users of GR and TK. Second, that serious academic criticism informs new recommendations to bring laws closer in line with the day to day reality and existing habits. It is in this sense that this thesis seeks to make an original contribution to the field by formulating a proposal of key elements useful for the implementation of ABS, extracted from the experience gained by the countries through the implementation of national laws.

3. Structure

Chapter 2 analyses information available from the ABSCH as of 15th March 2018 (this is the cut-off point for this study) to investigate how ABS functions in practice. ABSCH operates under the CBD, and provides data regarding legal developments on ABS measures, and the number and characteristics of the MATs signed up. The study of national and regional ABS laws as well as the MATs concluded, affords insight into the key elements that would be useful for a feasible implementation of ABS.

[213] Vogel and Ruiz (n 157)

Chapter 3 analyses ABS under the CBD and the NP texts to seek potential causes for its limited operability and effectiveness in achieving benefit-sharing. It concludes that the flaws and loopholes in the drafting of these instruments affect ABS operability. It ascribes this limitation to the countries' impossibility of agreement on essential aspects, such as access *ex-situ* and the public domain.

Chapter 4 considers ABS through the lenses of the CBD and its Protocol. It offers an explanation for certain basic elements, including concepts such as GR, TK, PIC, MAT, fair and equitable distribution of benefits, etc. The chapter concludes that ABS does not reflect practical reality, mainly because it only considers access to GR *in-situ*, and does not regulate the public domain or have a national/bilateral approach to compliance. These are identified as the problematic aspects of ABS.

Chapter 5 establishes how the CBD interlinks with the other international treaties which also govern the distribution of benefits derived from the use of GR and TK. It outlines the ABS systems adopted by the FAO and the WHO, and explains the manner in which they are intended to interact with the CBD. It will be seen that these norms were created to constitute a single international ABS system, with the separate treaties complementing each other to operate in a mutually-supportive way. However, in practice, it appears that these different systems function in a separate and uncoordinated way. The chapter concludes that one of the most severe consequences of this lack of coordination is that the rules of the CBD are not followed when GR is accessed in *ex-situ* conditions through the MLS of FAO.

Chapter 6 examines the relationship between ABS and IP. Apart from the long-standing claims regarding the lack of integration of the ABS rules within the text of TRIPS, this chapter emphasises the influence that the political will of the Parties of the CBD and the WTO have had in the implementation of ABS. The chapter recognises that, although a legal solution for the limited level of implementation of ABS can be proposed, solving this problem encompasses a political dimension which is not studied in depth here, but is used to offer some context when necessary to explain the way the ABS rules were built into the international fora and the difficulties it brings. The exposition emphasises that not only do ABS and IP laws not contradict each other, but that mutual respect is required when each is implemented. ABS should not obstruct the award of IPRs, yet grant of IPRs should take the ABS rules into account. The chapter concludes that, owing to the fragmentation and complexity of the international system of ABS, a distribution of benefits will be almost impossible to achieve unless a global solution is sought. This is why the conclusions include recommendations for the implementation of a global multilateral benefit-sharing mechanism GMBSM.

The conclusions of Chapter 7 comprise two aspects: the implementation of ABS at a national level and the creation of a GMBSM. First, it is concluded that the greatest obstacles faced by the countries when implementing ABS are: (i) the national/bilateral approach to the CBD; (ii) the exclusion of GR *ex-situ* from the CBD; and, (iii) the application of the concept of public domain in the ABS context. The impact on ABS is so great that the countries will probably continue to encounter obstacles in the application of their ABS laws until these limitations are

amended. However, because the flaws could only be modified through new negotiations, it is proposed, for now, that the creation of national ABS mechanisms be based on a mandatory obligation for the sharing of non-monetary benefits and a voluntary sharing of monetary benefits. This is a consequence of the difficulties in tracking and monitoring all uses of GR and TK as a necessary condition for obtaining a distribution of benefits, and the difficulties posed by the national/bilateral approach to compliance of the CBD.

Second, as it is considered that a GMBSM has a great potential to achieve benefit-sharing, additional key elements are proposed for its establishment. Among others are (i) a basic mechanism based on the same benefit-sharing scheme as previously proposed; (ii) a mechanism with global reach; and (iii) the use of a fund that functions in a similar way to the collective rights management societies, i.e., having in each country a responsible organisation for the collection and distribution of benefits.

CHAPTER 2. ABS in Practice

1. Introduction

The search for a feasible way to implement ABS necessarily requires an understanding of how ABS works in practice, the system as such, and the way it connects with other ABS systems and the IP law. In this regard, this chapter seeks to understand how ABS is implemented by the countries. For this purpose, the information provided by the Parties to the CBD and the NP to the ABS Clearing-House (ABSCH)[1] until 15th March 2018 is used in two aspects: the legal instruments developed, and the number of MATs subscribed.

The importance of reviewing this information is the possibility to have an approximate idea of what could be happening with ABS in practice and, therefore, what might be the suitable elements of an ABS mechanism.

2. Analysis of information provided by countries to the ABS Clearing House (ABSCH) of the CBD

The first thing to be noted is that countries with ABS developments are small in number when compared with the number of parties to the CBD and the Protocol (See Figure 1). As of 15 March 2018, the CBD has 196 State Parties, of which 105 are Parties to the Nagoya Protocol. Among all the Parties to the CBD and the Protocol, 57 countries have ABS legal developments (legislative, administrative, or policy measures),[2] 12 of which are Members only of the CBD, and 45 are also Members of the Protocol. Only 74 countries have delivered national reports on ABS implementation,[3] and only three have customary protocols, procedures, or laws in place

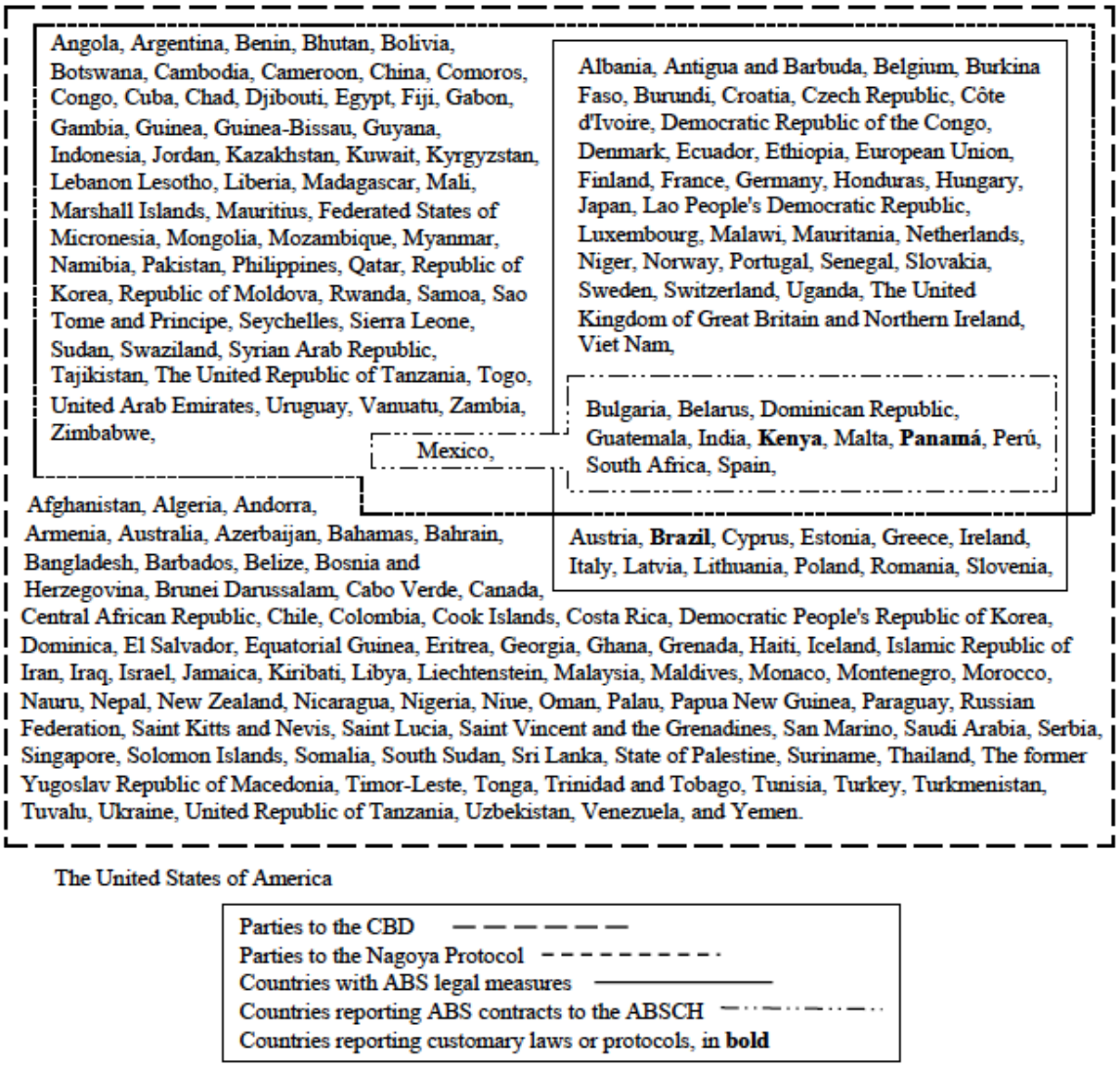
[1] The ABSCH was established by Article 14, paragraph 1, of the Nagoya Protocol as part of the Clearing-House Mechanism under Article 18, paragraph 3, of the CBD. This is the official on-line platform of the CBD created for the exchanging of information on access and benefit-sharing. There, Parties and Non-Parties of the Convention can have their own site to upload relevant information about their national experience on ABS. In this regard, the ABSCH has been designed to ensure that the countries will report the same aspects on ABS. Therefore, a set of on-line formats have been developed for the Countries to fill and make information available regarding: (i) ABS National Focal Point (NFP); (ii) Competent National Authorities (CNA); (iii) legislative, administrative or policy measures on ABS (MSR); (iv) national databases and websites (NDB); (v) checkpoints (CP); (vi) internationally recognised certificates of compliance (IRCC) – referred to ABS contracts or permits that can serve as an IRCC -; (vii) checkpoint communiqués (CPC); and (viii) interim national report on the implementation of the Nagoya Protocol.
More information about the ABS Clearing-House in:
CBD, 'Introduction to the Access and Benefit-Sharing Clearing-House (ABSCH)' <https://absch.cbd.int/help/about> accessed 05 October 2017

[2] It is important to point out that the EU is counted as if it was an independent entity of the countries of which is it composed, and, at the same time, the Andean Community of Nations and its countries, having an ABS law in place, are excluded.
Moreover, in a number of cases, the measures disclosed in the ABSCH are the Act ratifying the Nagoya Protocol (as in the case of Mexico), a strategy or plan, but not necessarily an ABS law.

[3] ABSCH, Interim National Reports on the Implementation of the Nagoya Protocol <https://absch.cbd.int/search/nationalRecords?schema=absNationalReport> accessed 01 April 2018

(Brazil, Kenya, and Panama). Among the countries with legal developments on ABS, only 12 have reported information to the ABSCH regarding ABS contracts or permits (MATs). These countries are Bulgaria, Belarus, Dominican Republic, Guatemala, India, Kenya, Malta, Mexico, Panama, Peru, South Africa, and Spain. Noteworthy is that Mexico, having no ABS regulations, reported the signature of three MATs, two for the access to GR and one for accessing TK.

Figure 1. ABS Developments



This table has been made by the author based on the information available on the ABSCH website and accessed on 15 March 2018

While the amount of legal and contractual developments on ABS reported to the ABSCH is small in number, we should not lose sight of the fact that some countries have over ten years of experience in ABS implementation. The importance of the knowledge gained during that time should not be overlooked, especially when limited practical experience with ABS exists.

The analysis of the mechanisms of implementation of ABS laws in some countries provides not only an idea of the ABS in practice, but some insights into the shortcomings and

strengths of the existing developments, and the ABS mechanisms the countries might be willing to implement in a GMBSM.

On that basis, the following sections analyse the information of the ABSCH regarding ABS legal developments and MATs subscribed. The first section looks at the scope of those laws and ABS obligations within the frame of the CBD and the Protocol. The second section examines the data of the MATs reported (134) to the ABSCH for accessing GR and TK.

2.1 Countries' legal developments on ABS

The CBD and the NP themselves do not provide for practical and effective solutions to accomplish benefit-sharing. These norms leave a number of issues unsolved for the countries to decide and regulate through their national laws. It was not until 2002 when the CBD produced the Bonn Guidelines on Access and Benefit-Sharing (the Bonn Guidelines) to guide the countries about the way national laws on ABS should be developed. Devising the Bonn Guidelines does not, however, solve those issues. For example, the Guidelines do not provide indications about the concepts of the CBD and, therefore, the scope of ABS remains unclear.[4]

In this context, some national ABS laws were created. Naturally, they reflect the countries' particular interests and, therefore, have different approaches to ABS. Cabrera Medaglia and López Silva characterise this regulatory process as (i) happening mostly in developing countries; (ii) having developed without international guidelines or consensus on how to construct them; and (iii) having been devised under the belief that the CBD and the NP were adequate, without modification to establish operative ABS systems.[5] Siebenhüner and Suplie note that, in addition, such a process has generally been accompanied by reflexive mechanisms consisting of the development of evaluations, specific committees, or topic-centred workshops in which the common elements of ABS are studied and/or discussed at the national and international levels.[6] As explained in Chapter 6, what these authors are referring to are what have been identified in international law as complex systems. In other words, the way ABS have been negotiated and implemented by the countries make it a complex system, which, in turn, could explain why they are experiencing obstacles for its implementation.

Despite this, to better understand the way ABS operates, it is necessary to know how the countries are applying the CBD and the NP. This is why ABS implementation through national laws is explored in the following sections. The first one shows the legal developments as contained in the CBD and the NP; the second describes the way some countries have regulated three aspects relating to the issues that, whilst they can be considered as part of ABS, were not included in the texts of the CBD or the NP. These three aspects are: GR *ex-situ*,

[4] On this particular issue, the Guidelines are limited to clarify that ABS is applied to all GR and associated TK covered by the CBD, but no definition or instruction on how the concepts of GR, TK, or access should be built are provided.

[5] Jorge Cabrera Medaglia and Christian López Silva, 'Addressing the Problems of Access: Protecting sources, while giving users certainty' (IUCN Environmental Policy and Law, Paper No. 67/1 2007), 4-5.

[6] Bernd Siebenhüner and Jessica Suplie, 'Implementing the Access and Benefit-Sharing Provisions of the CBD: A Case for Institutional Learning' (2005) 53 Ecological Economics 507, 517.

the public domain, and shared TK. The information contained in these sections was obtained from the ABS Clearing-House of the CBD (ABSCH), since this is the official website where the parties to the CBD provide information about legal aspects and practical implementation of ABS. The information analysed from the ABSCH is that which is available in English, Portuguese or Spanish; any information found in another language was not included, as the author is not proficient in other languages. For the selection of the countries, account was taken of the MATs subscribed; i.e., the laws of the countries reporting MATs were reviewed, provided they were disclosed to the ABSCH. National laws of the countries that are apparently using GR, as identified in Chapter 6, were also reviewed. This is why, despite the USA not being a member of the CBD or the NP, its regulations on ABS were included.

However, attention must be given to the fact that, because the number of measures available and, therefore, reviewed is small, it is not possible to draw general conclusions about the level of implementation and existent gaps in ABS norms. Nonetheless, this information is considered sufficiently indicative of trends for this subject.

2.1.1 National developments on aspects regulated in the CBD and the Nagoya Protocol

The information contained in the ABSCH shows that ABS has different levels of implementation. Some countries have only ratified the CBD and the NP, whilst others have different sets of measures that could include ABS laws, a strategy, guidelines, codes of good practice in research, and specialised government agencies which operate with more or less autonomy.

Noticeably, ABS legislation reproduces the objectives of the CBD and the NP, i.e., states having the aim to achieve the distribution of benefits derived from the use of GR and associated TK. Likewise, their own objectives, scope, definitions, requisites, obligations, competent authorities, procedures for obtaining PIC and MATs, infractions and sanctions, appear relatively clear in all of them. This does not mean, however, that the countries have limited themselves to reproducing the texts of the CBD and the NP. In fact, some of them, for example, have incorporated new elements to the ABS scope. A summary of the different ways in which the countries under study here have regulated ABS, can be seen in Table 1.

The parties of ABS transactions are the provider country and the user. National ABS developments endorse the sovereign rights of the states over their GR. On that basis, their exclusive right to concede PIC, subscribe MATs, and grant access is stated (Bulgaria,[7] Dominican Republic,[8] the Andean Community of Nations[9]). However, some differences can be observed in relation to the rights of ILCs over their TK and the GR located in their territories.

[7] Biological Diversity Act, 2017, Bulgaria. Articles 66.1, 66.3, 66.5

[8] Regulation of Access to Genetic Resources and Benefit-sharing (ABS) of the Dominican Republic, 2017. Article 12

[9] Decision 391 of 1996, Common Regime on Access to Genetic Resources, of the Commission of the Cartagena Agreement. Article 5

For example, although all countries studied uphold the principle that ABS processes must respect the rights of ILCs over their TK, few laws acknowledged their right to grant PIC for the access of GR located in their lands (the African Union,[10] the Andean Community of Nations,[11] Peru[12]).

Table 1. Legal Developments on Issues Regulated by the CBD and the NP

Scope	Parties	PIC, other permits	MATs/MTA	Process
Included: GR, TK, biological resources, biochemical elements, genetic heritage, derivatives, by-products, viruses, cell cultures, indigenous biological resources, information of GR and TK in databases. Excluded: GR from breeding programs, GR used as bulk commodities, derivatives, information and synthetic nucleoid acids, GR and TK accessed before the entry into force of the NP.	The country providing the resource and the user.	**PIC:** Generally the country providing the resources. Occasionally, the ILCs providing TK and for authorising the use of GR in their territories. **Other permits:** permits not entailing PIC may be required, some permits are required for accessing GR and TK, from: the owner, possessor or manager of the land where the biological resource containing the GR is located; the owner, possessor or manager of the biological resource; and the *ex-situ* conservation centre.	MATs are the common form for establishing benefit-sharing conditions. MTA can be a part of MATs, or could replace MATs for non-commercial use of GR.	Different ABS processes based on: - Nationality of the applicant, - Type of resource, - Intended utilisation, - Number of resources accessed - Transferring of research results, - Approval for seeking IPRs

Benefits	Mechanism for benefit-sharing	Relationship with IP	Controlling and Monitoring	Non Compliance
Monetary: Some countries establish the minimum percentage of their participation in the benefits, for example 10% of the research budget or 1% of the annual income from the economic exploitation of the resource. **Non-monetary:** capacity building, transfer of technology, collaborative research, sharing of results, disclosure of the origin of the resources.	All laws containing this subject matter have stipulated the creation of funds. Some countries prescribe that benefits could be received according to what has been agreed in MATs or retrieved from the fund.	All laws provide that access should not undermine IPRs. There could be specific obligations for obtaining IP protection, for example disclosure of origin and joint ownership of the IPRs. In few countries access can affect the granting of IPRs.	Usually consists in the requirement of information and development of collaborative research. It has been proposed the use of certificates (including fair trade), the creation of inventories, the use of barcodes, and a declaration of due diligence.	They mainly consist of: providing false information, collecting from non-authorised resources. Consequences: fines; MATs suspension, cancelation or revocation; other domestic penalties.

This table has been made by the author based on the information available on the ABSCH website and accessed on 15 March 2018

In general, the scope of ABS comprises both GR and TK. However, the EU[13] and Japan[14] only recognise rights to benefit from TK to the extent that such a right is regulated in the country of origin of the ILCs providing the TK. Some national developments have clarified the kind of resources that are or are not included in such scope, regardless of whether or not they are mentioned in the texts of the CBD and the NP. In this way, biological resources (India),[15]

[10] African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, 2000, Organisation of African Unity (OAU), Algeria. Article 5.1.i, 5.1.ii

[11] CAN (n 9). Article 35

[12] Supreme Decree No. 003-2009-MINAM, Regulation on Access to Genetic Resources, 2009, Peru. Article 6

[13] Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014, on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Article 2.4

[14] Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization. The Government of Japan. 2017. Chapter 3 No. 1.3

[15] The Biological Diversity Act, 2002, India. Article 2c

biochemical elements (Costa Rica,[16] Panama[17]), genetic heritage (Brazil),[18] derivatives (Bhutan)[19] or by-products (Dominican Republic,[20] the Andean Community of Nations,[21] the African Union, [22] India[23]), viruses and cell cultures (Bulgaria),[24] GR data (Belarus,[25] Brazil[26]), and indigenous biological resources (South Africa)[27] are included in ABS. Some countries exclude certain types of resources from ABS: GR obtained from breeding programs (Kenya),[28] GR used as bulk commodities, derivatives accessed independently of GR, GR acquired before the CBD (Malta),[29] information concerning GR and synthetic nucleoid acids (Japan),[30] and GR and TK accessed before the entry into force of the Nagoya Protocol (the EU,[31] Japan[32]).

Usually the obligation to distribute benefits is triggered by the 'use' of GR and TK, in the African Union, for example.[33] However, in some countries it is not the use but the 'access' which triggers the obligation to distribute benefits (Brazil,[34] Costa Rica,[35] India,[36] the Andean Community of Nations,[37] Panama[38]). Sometimes access has been broadly interpreted to include, for example, developing research activities or the production of technological developments, as happens in Brazil.[39]

The process for obtaining PIC is quite similar in the laws reviewed. Usually the applicant completes an application form with similar requirements: identification of the applicant, identification of the resource and identification of the geographical area where the samples will be collected, specification of the kind of research intended (scientific or commercial), and a description of the activities to be developed or a transcription of the research project. The

[16] Biodiversity Law, 1998, Costa Rica. Article 7.13
[17] Executive Decree No. 25 of 2009, Panama. Article 2
[18] Law 13, 123, 2015, Brazil. Article 2.1
[19] Access and Benefit Sharing Policy of Bhutan, 2015. Article 5
[20] Dominican Republic (n 8). Article 2
[21] CAN (n 9). Article 1
[22] OAU (n 10). Article 2.1.i, 2.1.ii, 2.1.iii, 2.1.iv, 2.1.v
[23] ibid, (n 15)
[24] Bulgaria (n 7). Article 118.10.3
[25] Resolution of the Council of Ministers of the Republic of Belarus, 1 October 2014, N933, On Establishment of the National Coordination Centre on Access to Genetic Resources and Benefit-Sharing. Deciding 2
[26] Brazil (n 18). Art. 2.I, 2.II
[27] National Environmental Management: Biodiversity Act, 2004, Republic of South Africa. Article 2a.iii
[28] The Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006, Kenya. Article 3b
[29] L.N. 379 of 2016, Environment Protection Act CAP. 549), Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations, 2016, Malta. Article 2.2b, 2.2c, 2.2g
[30] Japan (n 14). Chapter 1 No. 3.1.1, No. 3.1.2
[31] The EU (n 13). Article 2.1
[32] Japan (n 14). Chapter 1 No. 3.1.5
[33] OAU (n 10). Part Id
[34] Brazil (n 18). Article 1.I
[35] Costa Rica (n 16). Article 10.4
[36] India (n 15). 'An Act to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto.'
[37] CAN (n 9). Article 2
[38] Panama (n 17). Article 1a
[39] Brazil (n 18). Art. 2VII, 2IX

process of obtaining PIC for accessing GR is usually determined with relative clarity. However, the process of accessing TK is not always described, and regulations in this regard are commonly limited to stipulate that PIC must be conducted with the concerned ILCs in accordance with their customary laws and protocols.

Under some national developments, more than one person (for example, the owner of the land where the GR and TK are *in-situ* or the owner of the biological resource containing the GR) can concede a permit for access to the resource (the Andean Community of Nations,[40] Panama[41]), although in strict sense this is not a PIC—still, the permits are closely linked to PIC because their absence could obstruct access. ILCs also can grant PIC (the Andean Community of Nations,[42] the African Union[43], Ethiopia[44]), which is considered a pre-requisite for access (the African Union,[45] Costa Rica,[46] Brazil[47]). In other cases, accessing TK requires a joint PIC from the competent authority and the ILCs concerned (Malta,[48] Dominican Republic[49]). In Panama, any change of use or the transfer of the accessed resources requires a new PIC, and if a TK is involved, the PIC should include aspects related to IPRs.[50]

Although all provisions grant the respect and protection of TK, most of the countries reviewed have not designed specific rules for obtaining PIC from ILCs. Some establish that access should be done according to customary law and/or community protocols (Bhutan,[51] Brazil[52]). For others, the collective nature of TK is recognised (Brazil,[53] and Peru[54]), and PIC as condition for accessing TK is acknowledged (Peru).[55] Some countries establish the inalienability of ILCs' rights (the African Union[56]) and their indefeasibility (Peru).[57] TK protection can be found in the African Union,[58] and recognition of IPRs in Costa Rica[59] with independency of TK registration, declaration, or other formalities.

[40] CAN (n 9). Article 41a, 41b, 41c, 41d
[41] Panama (n 17). Article 25a, 25b, 25c, 25d
[42] CAN (n 9). Article 7
[43] OAU (n 10). Article 5.1.i, 5.1.ii
[44] Access to Genetic Resources and Community Knowledge, and Community Rights Council of Ministers Regulation No. 169/2009, Ethiopia. Article 21.1
[45] OAU (n 10). Articles 3.1, 18
[46] Costa Rica (n 16). Article 65
[47] Brazil (n 18). Articles 8.1, 9, 9.2
[48] Malta (n 29). Article 6.1
[49] The Dominican Republic (n 8). Article 9
[50] Panama (n 17). Articles 27, 28
[51] Bhutan (n 19). Article 6h
[52] Brazil (n 18). Art. 2.VII
[53] ibid, Article 10.1
[54] Law No. 27811 de 2002 of the Peruvian State. Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources. Article 12
[55] ibid, Articles 6, 23.1
[56] OAU (n 10). Article 23.1, 23.2, 23.3 and 23.4
[57] Peru (n 54). Article 10
[58] OAU (n 10). Article 23.3
[59] ibid

The Dominican Republic[60] defines PIC in the same way as prescribed in the ILO Convention 169 of 1989, while in Kenya it means an international procedure for exchanging, receiving, and handling notification and information by a competent authority.[61] Although ILCs' right to refuse access is implied in PIC, a few countries expressly incorporate it in their ABS laws (the African Union,[62] Costa Rica). Costa Rica particularly recognises the right of 'cultural objection',[63] consisting of the right of ILCs to oppose access to their resources based on cultural, spiritual, social, economic, and other reasons. Only the African Union law establishes the right for ILCs to withdraw PIC.[64]

In other countries, users are only obliged to obtain PIC when access is required for acquiring IPRs or for the commercial use of the accessed resources (the USA).[65] Japan does not require PIC for accessing GR existing in the country, unless the resources will be sent to another country.[66]

Access is always granted by a National Competent Authority. However, there is often more than one authority involved in ABS processes. Because of this, it is possible that users experience difficulties in identifying each of those competent authorities and their roles in the process of granting access. Because of that, by 29 March 2018, from among a total of 196 Parties to the CBD, only 53 have designated Competent National Authorities.[67] This figure is almost the same as the number of countries with ABS legal developments (57, see Figure 1). In addition, some countries have created different conditions for ABS processes based on:

i. Nationality of the applicant. For example, Brazil prohibits access to GR and TK of foreign natural persons,[68] and India requires the participation of a national person as a condition for access applications;[69]
ii. Type of resource. India has different process for accessing GR and TK, for seeking approval for transferring results of research, for seeking approval before applying for IP protection, and for third party transfers;[70]
iii. Type of intended utilisation. Costa Rica[71] and the Dominican Republic[72] have differentiated access for commercial and non-commercial purposes. Kenya[73] does not require ABS when access is intended for educational purposes and provided by

[60] Dominican Republic (n 8). Article 4i
[61] Kenya (n 28). Article 2
[62] OAU (n 10). Article 19
[63] Costa Rica (n 16). Article 66
[64] OAU (n 10). Article 20
[65] United States Department of the Interior. National Park Service. Director's Order #77-10: NPS Benefits Sharing, 2013. Available at: https://www.nps.gov/policy/DOrders/DO_77-10.pdf accessed in 01.03.2018. Articles 4.1.1, 4.2.1
[66] Japan (n 14). Chapters 4, 5
[67] ABSCH, 'the Access and Benefit-Sharing Clearing-House' <https://absch.cbd.int/> accessed 29 March 2018.
[68] Brazil (n 18). Article 11.1
[69] India (n 15). Article 3.2a, 3.2b, 3.2c.i, 3.2c.ii
[70] The Biological Diversity Rules, 2004, India. Articles 14, 17, 18, 19
[71] Costa Rica (n 16). Article 64
[72] Dominican Republic (n 8). Article 12a, 12b
[73] Kenya (n 28). Article 3d

national institutions. In all cases, there is the obligation to subscribe a new MAT when the original application changes from non-commercial to a commercial purpose. In Bhutan,[74] GR, when used as commodities, are excluded from ABS, except when later used for research and/or commercial purposes. The USA does not concede permits for commercial uses, and has different contract models based on the legal authority to use the agreement, the nature of the other party, or the type of benefits;[75]

iv. Number of resources accessed. Under the Andean Community of Nations[76] and Costa Rican[77] regulations, it is possible to obtain a single MAT for the utilisation of many GR and TK, as long as the resources accessed are part of a scientific research project developed by universities, research centres, or well-known researchers; and

v. Related activities. India provides processes for transfer of research results, approval for seeking IPRs, and third party transfers of GR or TK.[78]

It is usually established that MATs should be concluded in written form. Accounting documents such as permits (from the owner of the land or the biological resource containing the GR, the *ex-situ* collection, and the ILCs) and material transfer agreements (MTA) are also part of MATs. However, material transfer agreements are only required when GR are accessed in *ex-situ* conditions (Panama,[79] Peru[80]).

Many countries have models of MATs in place. The parties to MATs are generally a State, an ILC when the use of a TK is intended (Andean Community of Nations[81] and the African Union[82]), and a user. However, some restrictions could be imposed on users. For example, in the USA, only those who have a permit from the National Park Services can subscribe MATs.[83] Sometimes different national agencies participate as the body responsible for monitoring compliance with MATs and to receive the transfer of technology.

Under the USA law, PIC is not required, and the park authority grants MATs only for non-commercial purposes. Commercial permits are given if the applicant has entered into a Cooperative Research Development Agreement or other benefit-sharing agreement approved by the National Park Service.[84] While in Brazil, MATs are only required for the commercial use

[74] Bhutan (n 19). Article 5
[75] The USA (n 65). Articles 4.1.1, 5.2
[76] CAN (n 9). Article 36
[77] Costa Rica (n 16). Articles 63.3, 74
[78] India (n 15). Articles 4, 6.1
[79] Panama (n 17). Article 30
[80] Peru (n 12). Article 22
[81] CAN (n 9). Article 35
[82] OAU (n 10). Article 22
[83] National Park Service. Benefit-Sharing Handbook. 2018. The USA. Available at: <https://www.nps.gov/policy/DOrders/Benefits-Sharing_Handbook_(2018).pdf> accessed in 01.06.2019. Article 1.7
[84] The USA (n 65). Articles 4.1.1, 4.2.1

of GR and TK. In all other cases the samples of GR are accessed using material transfer agreements (MTAs).[85]

All reviewed laws include monetary and non-monetary forms of benefits. Almost all include a list with examples of benefits. Non-monetary benefits are expected from non-commercial MATs (Bulgaria),[86] and are usually identified as capacity-building, transfer of technology, the participation of nationals in research projects, the sharing of research results, and the disclosure of the origin of the resources in scientific publications (India,[87] Peru[88]).

Some countries establish the minimum percentage of their participation in the benefits (Costa Rica,[89] the African Union,[90] Brazil[91]). In Brazil, when the monetary benefits are derived from the economic exploitation of GR *ex-situ*, a percentage of the monetary benefits will be directed towards the collection,[92] and no benefit-sharing from the use of GR is required when the benefits from the use of TK have been distributed.[93] Others provide details regarding the purpose for which the benefits obtained should be invested, such as the conservation of biodiversity and the promotion of community knowledge (Ethiopia).[94]

Most of the laws reviewed provide for the creation of funds, and have established two ways for the distribution of benefits. First, direct distribution of benefits between the country of origin and the user of GR (the Andean Community of Nations,[95] the EU,[96] the USA,[97] Japan[98]) and TK in accordance with MATs (Bhutan),[99] or directing the benefits towards a fund (Ethiopia,[100] India[101]). Under the Andean Community of Nations legislation, ILCs can directly negotiate the benefits,[102] while in Malta,[103] they are negotiated by the national authority. Second, through depositing the sum agreed in a fund (Costa Rica,[104] Brazil,[105] Peru,[106] South Africa[107]). The resources of such funds are usually composed of the money received as a share of benefits, other payments derived from access activities (licences, royalties), duties and

[85] Brazil (n 18). Article 2.XIX
[86] Bulgaria (n 7). Article 66.4
[87] India (n 70). Article 20.2
[88] Peru (n 12). Article 23c, 23d, 23e, 23f, 23g, 23h, 23i
[89] Costa Rica (n 16). Article 75
[90] OAU (n 10). Article 22
[91] Presidency of the Federative Republic of Brazil. Civil House. Legal Sub-Office. Decree 8.772 of May 11 of 2016. Articles 20, 21, 24
[92] Brazil (n 18). Article 32.II.2
[93] ibid, Article 25.3
[94] Ethiopia (n 44). Articles 27.1, 28
[95] CAN (n 9). Article 1
[96] The EU (n 13). Article 4.2
[97] The USA (n 65). Article 4.3.1
[98] Japan (n 14). Chapter 3 No. 1.1
[99] Bhutan (n 19). Article 8.4.9
[100] Ethiopia (n 44). Article 26.1
[101] India (n 15). Art. 21.3
[102] CAN (n 9). Article 35
[103] Malta (n 29). Article 6.2
[104] Costa Rica (n 16). Article 114
[105] Brazil (n 18). Articles 24.2, 25.II.1, 25.II.4
[106] Peru (n 54). Article 8
[107] South Africa (n 27). Article 85.1

taxes, resources from the government, donations, and fines for infractions to the ABS law. Although it is usually established that the resources from the fund will be used for biodiversity preservation, some laws indicate the right of ILCs to be recipients. In those cases, the ILCs can retrieve resources from the fund to finance the development of communal projects (Brazil,[108] the African Union,[109] Ethiopia,[110] Peru[111]). In India, monies of the fund can be used for repairing any damages caused by the access activities.[112]

The relationship between ABS and IP has been limited to the obligation of States to respect existing IPRs when conceding access, as well as their obligation to ensure that IPRs have been granted respecting the ABS rules. Some countries have incorporated specific obligations when ABS relates to IPRs. For example, in granting IP protection, Costa Rica requires the certificate of origin of the resource and proof that PIC was obtained.[113] India stipulates that the distribution of benefits when access involves the acquisition of IPRs should be solved on a case-by-case basis through MATs.[114] In few countries, ILCs' rights over their TK can affect the granting of patent rights (in Costa Rica, IPRs are granted only if PIC has been obtained,[115] the Andean Community of Nations[116]); some other recognise IPRs over TK in favour of ILCs (the African Union,[117] Costa Rica[118]).

Similar measures for controlling and monitoring the use of GR and TK have been established in ABS laws. Controlling activities mainly consist of the obligation to develop collaborative scientific research, to disclose the origin of the resources (Brazil,[119] Costa Rica,[120] India,[121] Peru[122]), and the request for information (Andean Community of Nations,[123] the Dominican Republic[124], Japan[125]). Under the EU law monitoring is performed by requesting all recipients of research funding involving the utilisation of GR and TK associated with GR to declare that they exercise due diligence.[126]

[108] Brazil (n 18). Article 19.IIa
[109] OAU (n 10). Article 66.4
[110] Ethiopia (n 44). Article 31.1, 31.2
[111] Peru (n 54). Articles 37, 38
[112] India (n 15). Article 32.2b
[113] Costa Rica (n 16). Article 80
[114] India (n 15). Article 6.1, 6.2
[115] ibid, Article 80
[116] Decision 486 of 2000, Common Provisions on Industrial Property, of the Commission of the Cartagena Agreement. Article 3
[117] OAU (n 10). Article 23.1, 23.2, 23.3, 23.4
[118] Costa Rica (n 16). Article 82
[119] Brazil (n 18). Article 10.II
[120] Costa Rica (n 16). Article 71
[121] India (n 70). Article 14.6.ii, 14.6.iii, 14.6.ix
[122] Peru (n 12). Article 23c, 23d, 23k, 23l
[123] CAN (n 9). Article 18
[124] Dominican Republic (n 8). Article 26a
[125] Japan (n 14). Chapter 2 No. 5.1
[126] The EU (n 14). Article 7.1

Another means of monitoring GR and TK has been the creation of inventories of national biodiversity and associated knowledge (Bhutan,[127] India,[128] Peru[129]), and the use of barcodes (the Dominican Republic).[130]

For these purposes, the EU[131] and Japan[132] have suggested the use of an internationally-recognised certificate of compliance, records of access and disclosing the information to the ABS Clearing-House, with the exception of the commercial or industrial information, which is confidential. The African Union stipulates the use of a certificate of fair trade when a significant part of the benefits go back to the concerned ILCs.[133]

Some prohibitions have been established such as: (i) sharing the accessed resources without prior consent in written form (Bulgaria,[134] India[135]) or under different conditions from those under which they were received (Panama,[136] Peru[137]); (ii) sharing the research results (India)[138]; and (iii) claiming IPRs over the accessed resources (India)[139] and their by-products (Peru).[140] Also, providing false information, collecting samples of non-authorised material, or collecting authorised GR in non-authorised sampling locations are commonly considered as violations to the ABS law. The consequences from infringements to ABS regulations are almost identical in the laws reviewed. These are usually fines and administrative sanctions, including MATs suspension, cancellation, or revocation and, where applicable, other domestic penalties (Costa Rica[141], India[142]).

2.1.2 National developments on aspects not regulated in the CBD or the NP

As explained in sections 3.2 and 3.3 of the next chapter, some important aspects have been left out of the scope of ABS. Although they were not initially contemplated in the CBD, the State Parties tried to reach an agreement during the negotiations of the NP, but with no positive results. Thus, they are not regulated by the CBD and the NP. In this thesis, those aspects have been grouped in two: non-agreed issues of the Draft Text of the NP, and one issue that was not discussed during the negotiations of the NP. The first group comprehends (i) the use of pathogens and viruses, and their relationship with the WHO Pandemic Influenza Preparedness (PIP) Framework; (ii) GR for food and agriculture; (iii) access through *ex-situ*

[127] Bhutan (n 19). Article 8.2.1
[128] India (n 15). Article 36.1
[129] Peru (n 54). Article 16a, 16b
[130] Dominican Republic (n 8). Article 27e
[131] The EU (n 13). Article 7.2a, 7.2b, 7.3, 7.5
[132] Japan (n 14). Chapter 2 No. 1.2, 4.1
[133] OAU (n 10). Article 27.2
[134] Bulgaria (n 7). Article 66.5
[135] India (n 70). Article 19.1
[136] Panama (n 17). Note 44, Article 27
[137] Peru (n 12). Article 23b, 23j
[138] India (n 15). Article 4
[139] India (n 70). Article 18.1
[140] Peru (n 12). Article 23a
[141] Costa Rica (n 16). Article 112
[142] India (n 70). Article 15.1.i, 15.2

conservation centres; (iv) publicly-available TK; and (v) GR in the Antarctic Treaty Area and marine GR from areas beyond national jurisdiction. The non-discussed issue is the use of genetic sequence data in conjunction with technologies that would allow the use of GR without the need of having physical access to these resources, i.e. what could be regarded as 'use without access'.

Few countries have regulated only three of those issues through their national laws, namely: GR *ex-situ*, the public domain, and shared TK. The cause for that is possibly related to the difficulties experienced during the NP negotiations. Nonetheless, these legal developments are of utmost importance, not only because they offer solutions for some of the most controversial aspects of ABS, but also because the results of their implementation could provide valuable insights about the effectiveness of these solutions. For these reasons this section is dedicated to their explanation.

One of the non-agreed issues regulated in national laws is access through *ex-situ* conservation centres. This has been done in two different ways: in association with the MLS of FAO, and irrespective of whether or not the *ex-situ* centre providing GR forms part of the MLS.

Regarding the MLS, and as it will be explained in Section 2.3 of Chapter 5, through Resolution 7/93 the FAO requested a forum for negotiations among governments 'for consideration of the issue of access on mutually agreed terms to plant genetic resources, including *ex-situ* collections not addressed by the Convention.' As a result, the MLS (as an ABS system) was included in the International Treaty on Genetic Resources for Food and Agriculture (ITPGRFA) of 2001. Section 2.6 of Chapter 5 deals with the MLS, however, it is useful to recall here that Articles 11.5 and 12.1 of the ITPGRFA establish that the MLS was created for the facilitated access of the plant GR listed in Annex I of such instrument, for their use in food and agriculture, and held in the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR) and in other international institutions. This means that the MLS has a particular scope and different nature than the CBD. Thus, the use of the MLS aiming at achieving compliance with the CBD could create confusion and legal gaps in its application.

Despite this, the MLS is used as a reference point for ABS regulations in Bhutan. This way, accessing GR *ex-situ* through the MLS generates benefit-sharing obligations in that country.[143] In contrast, under EU law no benefits are due when access is gained through an *ex-situ* centre whether or not it is part of the MLS. This means that unlike Bhutan, in the EU accessing GR from an *ex-situ* centre forming part of the MLS does not generate benefit-sharing obligations. To come to this understanding in the EU law, it was assumed that GR *ex-situ* are in the public domain which, in turn, implies that they are free to use; and it was established that accessing GR through the MLS constitutes an exercise of 'due diligence'.[144] It was also stated that accessing GR *ex-situ* from a collection included in the register of collections within the Union is deemed to satisfy due diligence requirements, i.e., it is assumed that the GR held in those collections were accessed in accordance with the ABS law of the provider country, and

[143] Bhutan (n 19). Article 8.5.5
[144] The EU (n 13). Article 4.1, 4.4

that the benefits were fairly and equitable shared upon MATs.[145] In this way, users of the MLS in the EU are not required to conduct ABS. These users are only obliged under the terms of the MTAs subscribed with the *ex-situ* centre. The problem with such MTAs is that they are usually limited to settling the conditions for the transfer of the samples to be accessed, but they do not generally contain obligations regarding the distribution of benefits with the country of origin.

Although the EU approach could be seen as a reasonable way to deal with access to GR *ex-situ*, some comments are required. On the one hand, it must not be overlooked, as explained above, that the ABS scope of the CBD and the FAO are different. In a strict sense, this means that any access to and distribution of benefits arising from the use of all national GR which is not human, not listed in Annex I of the ITPGRFA, or not a virus used for pandemic vaccine production (regulated by the WHO), must be conducted following the ABS rules of the CDB. In addition, accepting that all GR *ex-situ* should be considered to be placed in the public domain could meet strong opposition from provider countries of GR. Access *ex-situ* is consistently identified as one of the most serious failures of the ABS system of the CBD, because, among other things, it seems that the majority of accessions to GR *ex-situ* is made through the MLS, which limits the possibility for providers to directly receive the distribution of benefits derived from their use. Nonetheless, GR *ex-situ* can be deemed as a part of the public domain if new agreement on it is reached among the Members of the CBD.

On the other hand, as explained in Chapter 5, it should not be forgotten that for a long time, *ex-situ* conservation centres operated under the philosophy of the free sharing of biological materials and their related information (which includes GR) as a necessary condition for the advance of science and the benefit of humankind. That means that there is a high probability that the *ex-situ* centres had acquired GR without following the CBD rules on ABS, even when this Convention had already entered into force. There is, therefore, a critical point for which it does not seem reasonable to assume that all GR in *ex-situ* conservation centres were acquired in accordance with the CBD or before it entered into force, meaning that due diligence cannot be presumed when accessing GR *ex-situ* through these centres.

Regarding regulations on access through *ex-situ* collection centres, irrespective of whether or not they form part of the MLS, under the Panamanian law, *ex-situ* centres have the obligations to declare before the National Authority all the biological material under their possession and to subscribe MTAs every time a biological or a genetic resource is provided.[146] The obligation for obtaining PIC only exists when the access includes the use of a TK. In a similar way, Peruvian law provides for the subscription of MTAs, with the difference that these agreements must be previously approved by the National Competent Authority.[147] MTAs determine the conditions for the accession, the recognition of the origin of the resources, an obligation to not transfer the material accessed without authorisation, and the prohibition to claim IPRs over the accessed resources. *Ex-situ* collections can only provide GR for non-

[145] ibid, Article 4.7
[146] Panama (n 17). Articles 29, 30
[147] Peru (n 12). Articles 29, 30

commercial purposes. This law is, however, silent regarding how to proceed when the utilisation of the resource accessed *ex-situ* changes from non-commercial to commercial. However, it could be assumed because the Community law (from which it follows) establishes the need for a new agreement to decide the way in which the benefits will be distributed.

In Bulgaria, samples deposited in *ex-situ* collections should disclose its country of origin.[148] In the Dominican Republic, collecting GR for its preservation in *ex-situ* centres is not in the ABS scope unless those samples are used for R&D activities.[149] Under the Andean Community of Nations legislation and Bhutan,[150] GR *ex-situ* are in the ABS scope, and in the Andean Community of Nations, *ex-situ* centres have to subscribe MATs with the country of origin when acting as providers of GR.[151]

Regulations of both GR and TK in the public domain have been found in some national developments on ABS. Of all the laws analysed, Costa Rica is the only country ruling on access to GR in the public domain. Interestingly, under this law, all GR and TK are in the public domain, but the State retains the right to control and benefit from their use.[152] Additionally, the concept of GR has been understood in its broad sense as 'biochemical and genetic components' which, in practical terms, can be deemed as equivalent to 'biodiversity'.[153] Therefore, in Costa Rica, the access to any element of biodiversity and associated TK (*in-situ*, *ex-situ* or in the public domain) triggers the obligation to distribute benefits. Similarly, under the African Union law, ILCs do not lose the right to benefit from disclosed GR and TK.[154]

In Panama[155] and Peru,[156] users have the obligation to distribute benefits provided they are the country of origin of the accessed TK in the public domain. The benefits shall be deposited in an account of the national fund to be invested in the training of ILCs on how to strengthen and defend their TK and cultural identity.[157]

Under Brazilian law, a distribution of benefits is mandatory any time Brazilian TK is used, regardless of whether or not it is in the public domain, and regardless of the possibility of linking the knowledge to a particular community or group of communities. Attention is drawn to the way in which the origin or provenance of TK can be proved. Under this law, the common understanding respecting the way in which immaterial assets are placed in the public domain, i.e., making the knowledge publicly accessible, is used precisely to demonstrate their origin. In this way, scientific publications, registers, databases, and inventories showing the Brazilian origin of a given TK serve to prove its origin and, therefore, to legally claim the right to receive a distribution of benefits.[158]

[148] Bulgaria (n 7). Articles 58.1, 60.2.1
[149] Dominican Republic (n 8). Article 3f
[150] Bhutan (n 19). Article 6c
[151] CAN (n 9). Article 37
[152] Costa Rica (n 16). Article 6
[153] ibid, Articles 7.1, 13, 14
[154] OAU (n 10). Article 23.4
[155] Panama (n 17). Article 35
[156] Peru (n 54). Article 13
[157] Panama (n 17). Article 38.1a; Peru (n 54). Article 37
[158] Brazil (n 18). Articles 8.3.I, 8.3.II, 8.3.III, 17.II.6, 24.2

Dominican Republic law does not expressly affirm that TK in the public domain is within the ABS scope, but it stipulates that TK can be found in oral or documented forms among others.[159]

The distribution of benefits of shared resources appears to be one of the most difficult issues to solve in ABS regulations. As explained in Chapter 2, the Nagoya Protocol suggests the creation of a mechanism for the distribution of benefits of shared resources in transboundary situations. An example would be when the same TK is shared by communities belonging to different countries or living at their frontiers, or when PIC cannot be obtained, e.g., when more than one community has the same TK and no legislation has been established to solve such a situation.

So far, no country has yet implemented the mechanism suggested in Article 10 of the Protocol. Nonetheless, some countries have regulated the distribution of benefits arising from the use of shared TK. For example, Bhutan establishes that when a TK is held by more than one ILCs, all should enter into negotiation with the user, and, if not possible, to rely on the National Focal Point who will negotiate on behalf of the communities.[160] Ethiopia determines that the benefits should be shared among the concerned ILCs according to their relative contribution to the conservation of GR and/or TK.[161] In Brazil, the user can obtain PIC and sign a MAT with the ILC of their election among all those ILCs who are acknowledged as owners of the TK. That ILC is deemed the provider of the shared TK and will directly benefit from its utilisation according to what was agreed (MAT).[162] The other ILCs that also own the same TK can benefit from its use by obtaining resources from the National Fund for the Distribution of Benefits, where the user has to deposit 50% of the annual net revenue obtained from the economic use of the accessed TK or what has been agreed in the sectorial agreement.[163] Importantly, it will be always presumed that more than one ILC holds the same TK every time TK is accessed.[164]

Based on the previous information, the main conclusion is that ABS regulation reflects the contents of the CBD and the NP. However, as earlier stated, these laws also reveal the particular interests of each country and, consequently, present differences. Some aspects appear more sensitive than others; for example, at the same time information on GR and TK, GR *ex-situ*, and derivatives are included and excluded from the ABS scope. Also, although all laws reviewed recognise PIC as one of the elements of ABS, the instructions about how to proceed to obtain it seem less clear than instructions about other ABS aspects. Other aspects are problematic as well, for example, the possibility that infractions to ABS obligations can undermine IPRs, expanding the scope of ABS to information, derivatives, by-products, and the use of new biotechnological tools (synthetic biology and bioinformatics). In addition, Cabrera Medaglia and López Silva note that studies on ABS legal developments often report similar limitations in the laws: their extent of scope and coverage; cumbersome application process;

[159] Dominican Republic (n 8). Article 4h
[160] Bhutan (n 19). Article 8.4.10
[161] Ethiopia (n 44). Article 29.2
[162] Brazil (n 18). Article 24.1, 24.2
[163] ibid, Articles 20, 24.3, 24.4
[164] ibid, Article 24.5

difficulties involving PIC; complexity of institutional mechanisms; and the level of demand imposed under ABS legislative requirements.[165] Those aspects were also identified in an empirical research conducted on the MATs subscribed in Colombia. The study concluded that ABS implementation is hindered by the lack of clarity in the Colombian ABS law regarding the mechanisms for obtaining PIC, the competent authority or authorities dealing with each part of the process, and the excessive bureaucracy of these processes.[166]

Finally, some matters appear to be generally accepted by the countries. MATs are the common form for establishing benefit-sharing obligations and some countries have developed models of standards MATs, the participation of nationals in research activities, the sharing of research results, the convenience of disclosing the origin of the resources and activities regarding the use of the resources, the use of certificates as a means to demonstrate the legal access, the need to respect the IPRs granted over creations based on the accessed resources, and the creation of funds for collecting and distributing the benefits. On this latter point, it is important to note that none of the laws studied contains a different way to manage the monies derived from ABS activities. This finding may indicate that the countries would be more likely to accept a fund as the modality to operationalise the GMBSM of Article 10 of NP.

A summary of the legal developments made by the countries previously considered in this section, on issues not regulated by the CBD and the NP are presented in the table below.

Table 2. Legal Developments on Issues Not Regulated by the CBD and the NP

GR *ex-situ*	The Public Domain	Shared TK
Within the MLS of FAO: - Some laws prescribe no benefit-sharing obligations exist given compliance with the due diligence principle. - Others stipulate benefit-sharing obligations: directing a percentage of the benefits to a fund. **Outside the MLS of FAO:** - In some cases access is possible simply by subscribing MTAs, but only for non-commercial purposes, and usually with limitations for the sharing of samples and seeking protection through IPRs. - In some others access always requires MATs between the country of origin and the user and a MTA between the *ex-situ* centre and the user. In this case, non-commercial use generates the obligation to share non-commercial benefits.	One country considers that all GR and TK is in the public domain, but reserves the right to grant access. In other countries GR and TK may not be in the public domain, and, in such cases, benefit-sharing obligations exist provided the origin of the resources can be ascertained. In this case the benefits should be deposited in a fund.	There are three ways in which the countries have regulated shared TK: - Granting the right to all concerned ILCs to negotiate the benefits with the user. If no agreement could be achieved, the national authority will negotiate on behalf of all ILCs. - The national authority negotiate the benefits and distribute them among all concerned ILCs according to their relative contribution to conservation of the GR and/or TK accessed. - Direct negotiation between the user and one ILC of their election, and the deposit of a determined amount of money to a fund, from which the ILCs sharing the same TK can retrieve the benefits through the submission of communal projects.

This table has been made by the author based on the information available on the ABSCH website and accessed on 15 March 2018

[165] Cabrera Medaglia and López Silva (n 6), 8-9.

[166] Dalí Aleixandra Rojas Díaz and Gabriel Ricardo Nemogá Soto, 'Algunas Lecciones Sobre el Acceso a Recursos Genéticos en Colombia. Dos Estudios de Caso' (2009) 14(2) Acta Biológica Colombiana 137, 138-139, 158-159.

2.2 ABS contracts

In regards to ABS contracts/permits (MATs), the countries can report to the ABSCH about: (i) issuing authorities; (ii) reference numbers; (iii) dates of issuance; (iv) any additional information; (v) if PIC was provided; (vi) general information about MATs; (vii) conditions for third party transfer; (viii) accessed resources; (ix) resource utilisations; and, (x) user's nationality and sector (government agency, academic or research institute, and private sector).

Thus, as of 15 March 2018, notification of the issuance of 143 MATs has been provided. Of these, 134 were for accessing GR and 9 for accessing TK. Belarus, the Dominican Republic, Malta, and Peru each issued one MAT, Guatemala two, Bulgaria and Mexico three each, Spain four, Kenya five, Panama 12, South Africa 24, and India 86. During the years 2018, 2013, and 2008, only one agreement was signed; there were 14 in 2014, 25 in 2017, 44 in 2015, and 57 in 2016 (See Table 3).

Table 3. Countries' Report on the Number of Contracts/Permits Disclosed to the ABSCH

Countries	2008	2013	2014	2015	2016	2017	2018	Total/ Country
Bulgaria				1		2		**3**
Belarus							1	**1**
Dominican Republic	1							**1**
Guatemala				1	1			**2**
India			5	34	43	4		**86**
Kenya			4		1			**5**
Malta						1		**1**
Mexico				1	1	1		**3**
Panama					4	8		**12**
Peru						1		**1**
South Africa		1	5	7	7	4		**24**
Spain						4		**4**
Total/year	**1**	**1**	**14**	**44**	**57**	**25**	**1**	**143**

Overall total

This table has been made by the author based on the information available on the ABSCH website and accessed on 15 March 2018

Although 12 countries providing information on MATs to the ABSCH is a small amount considering the number of States Parties to the CBD and the Protocol (196), and the number of countries having national measures on ABS (57), the number of MATs reported is not so small (134). Given this, it is expected that analysing such MATs can provide an indication of the way in which those countries are currently implementing ABS. In that regard, this section systematises the information provided to the ABSCH on MATs concerning the accessed

resource (GR or TK), its intended use (commercial, non-commercial), the characteristics of the applicant (national/foreigner, academic or research institute/governmental agency/private sector), and the amount of information that has been classified as confidential.

The first thing to be noted is that this information does not provide a clear view of the impact of the Protocol on ABS implementation. This is first because the information on the ABSCH is incomplete and, second, because the countries do not exhibit a similar behaviour towards the issuance of MATs. For example, India, which is the country with the largest number of notifications in this regard (86 MATs), reported the issuance of five contracts in 2014, 34 in 2015, 43 in 2016, and four in 2017. The number of contracts produced during the years 2015 and 2016 were similar, while there was an evident decrease in 2017. Based on this information, it cannot be suggested that India has experienced an expansion in ABS implementation. Moreover, it is unlikely that such a difference is due to a reduction in ABS transactions. Instead, it appears that for one reason or another, at some point during 2017, India stopped reporting to the ABSCH. In contrast, South Africa, the country with the next highest number of MATs reported (24), has shown stable issuances. For its part, Kenya recorded the issuance of four contracts in 2014 (three before the entry into force of the Protocol) and just one in 2016, i.e., this information shows a higher activity on ABS transactions before the Protocol. Notwithstanding the foregoing, the figures show an increase in the number of MATs produced since the entry into force of the Protocol (see Table 3).

Table 4. Information on Contracts/Permits for Accessing GR

Countries	Conf. All	Conf. Use and user/ Non-Comm	Conf. Use and User/ Comm	Conf. Use/ User Nal	Non-Comm/ User Nal			Non-Comm/ User Ext			Comm/ User Nal			Comm/ User Ext			Total/ Coun-try
					G	A	P	G	A	P	G	A	P	G	A	P	
Bulgaria	1	2															3
Belarus								1									1
Dominican Republic					1												1
Guatemala						2											2
India	23	2	25	1					7		1	18	5		1		83
Kenya		2							3								5
Malta		1															1
Mexico									1						1		2
Panama					1	4			7								12
Peru							1										1
South Africa												6	13				19
Spain		4															4
Total/Contracts	**24**	**11**	**25**	**1**	**2**	**6**	**1**	**1**	**18**		**1**	**24**	**18**		**2**		134

G: Government Agency
A: Academic or Research Institute
P: Private Sector

This table has been made by the author based on the information available on the ABSCH website and accessed on 15 March 2018

The second important point is the fact that 63 (61 on GR and two on TK) out of 143 MATs have confidential information. This means that almost half of the information (47%) is unknown (See Tables 4 and 5).

In 25 MATs (24 on GR and one on TK), the information about the resource accessed, its intended use (commercial or non-commercial), and the user (nationality and sector) is confidential. In this regard, it should be pointed out that this information is vital to knowing how the access has been conducted. From Tables 7 and 8 show that in 25 MATs for accessing GR with commercial purposes, it is not possible to know who the user is. In two contracts, the intended use is confidential, one for accessing GR with a national user and the other for accessing TK with a foreigner user. In 36 contracts on GR, the resource and the user are confidential; 11 MATs are for non-commercial purposes, and 25 are for commercial purposes. In one MAT for accessing TK, the resource is confidential and the user is foreign. This mean that it is not possible to know which TK has been used, and the fact that the user is located in a foreign jurisdiction makes it more difficult. Therefore, the possibility to sign a new MAT in the case of a change in the intended use from non-commercial to commercial is even more remote.

It is remarkable that the MATs reported by the Dominican Republic, Guatemala, Panama, Peru, and South Africa have no confidential information. This could be interpreted as indicating that provider countries (with the exception of India) are more willing to disclose information than user countries. The problem of keeping confidentiality over some vital information on ABS is that it could be counterproductive for developing activities of controlling and monitoring the use of GR and TK, which, in turn, is counterproductive for achieving ABS compliance. In addition, 16 MATs on GR do not disclose the information about transfer permits with third parties (See Table 6) and, consequently, it is not be possible to know if those users have been authorised to transfer samples of the materials accessed to third parties.

Table 5. Information on Contracts/Permits for Accessing TK

Countries	Conf. All	Conf. Transfers	Conf. Auth. Granting PIC	Conf. Use/ User Ext.			Non-Comm/ User Ext.			Comm/ User Nal.			Total
				G	A	P	G	A	P	G	A	P	
India	1		2		1			1					3
Mexico		1							1				1
South Africa											3	2	5
Total/ Contracts	**1**				**1**			**1**	**1**		**3**	**2**	9

G: Government Agency
A: Academic or Research Institute
P: Private Sector

This table has been made by the author based on the information available on the ABSCH website and accessed on 15 March 2018

Also, of concern is the fact that in 38 MATs on GR and two on TK, it is not possible to know who the authority granting PIC was. Moreover, in two MATs on TK this information is confidential (see Tables 4 and 5). This might be especially problematic for accessing TK because, with the exception of the Andean Community of Nations, in all ABS laws reviewed in the previous section, PIC has to be granted by the traditional authority representing the ILCs who owns the TK. This information should be public to ensure that such an obligation has been performed.

When the type of intended use of the accessed resources in non-commercial, 30 MATs were public, 28 were for accessing to GR, and two for accessing to TK. Among the MATs on GR, nine have national users (two governmental agencies, six academic or research institutes, and one from the public sector), and 19 foreigner users (one governmental agency, and 18 academic or research institutes). The two non-commercial MATs on TK were signed with foreign users, one academic or research institute and the other with a user form the private sector.

Among the 50 MATs with commercial purposes, 45 are for accessing GR and five for accessing TK. Among the MATs on GR, 43 have national users (one governmental agency, 24 academic or research institutes, and 18 from the public sector), and two foreign users from academia. The five MATs on TK have national users, three from academia, and two from the private sector.

In sum, 50 MATs have commercial purposes and 30 have non-commercial purposes. This number supports the idea of the great economic potential of GR and TK utilisation, previously expressed in Section 4 of Chapter 5 in regards to patent activity.

Table 6. Undisclosed Information on Contracts/Permits for Accessing GR

Countries	MATs	Transfer Permits	Total Contracts
Bulgaria	2	1	**3**
Belarus			**1**
Dominican Republic	1	1	**1**
Guatemala			**2**
India			**83**
Kenya			**5**
Malta			**1**
Mexico		1	**3**
Panama			**12**
Peru	1	1	**1**
South Africa			**19**
Spain	4	4	**4**
Total/Inform.	**8**	**8**	**134**

This table has been made by the author based on the information available on the ABSCH website and accessed on 15 March 2018

It is quite remarkable that out of 143 MATs, only nine are for accessing TK. This represents 6.3% of all these instruments. Five have commercial purposes, two non-commercial purposes, and the remaining two, the information is confidential. Three of the applicants were foreigners, one was national, and the nationality of the remaining is unknown. Two of the applicants work in academia, two in the private sector, and for the last the information is confidential. Although nine of 143 seems a small sample, it should be stressed that five of those nine, i.e., more than half, have a commercial purpose. As already stated, this may indicate that there is a real interest in the commercial use of TK.

According to the available information on the ABSCH, ABS processes appear to be primarily developed by national applicants working at universities or research institutes conducting commercial research (50 commercial contracts/permits in contrast to 30 non-commercial; see Tables 7 and 8). National users (56) are around twice as common as foreign users (24). However, this does not necessarily mean that nationals are predominantly using GR and TK. For example, as explained in Section 2.1.1 C of this chapter, India requires the participation of a national person as a condition for access applications. This combined with the fact that India is the country with the largest number of MATs reported to the ABSCH (86) may be affecting the overall average of participation of national applicants in ABS activities.

Notwithstanding the above, the high participation of nationals in ABS processes could also indicate that users might find it easier to conduct ABS processes within their own country. This idea is supported by the data retrieved from the official web site of the International Treaty (ITPGRFA) of the FAO. Accordingly, as of 12 April 2018, the samples provided by 41 countries were transferred to recipients located in another 179 countries.[167] As observed, the number of foreign users of GR is more than four times the number of providers. Because of this, it is logical to suppose that the small number of MATs subscribed by foreign applicants is not related to their lack of interest in using the GR located in other jurisdictions. Otherwise, the same behaviour should be observed in the number of accessions to GR conducted through the MLS, but this is not the case. This might prove that fragmentation and complexity of ABS pose major obstacles for foreign applicants who have to know and understand different ABS laws, requirements, and processes developed by provider countries.

In addition, the amount and quality of the information contained in the ABSCH seem to indicate that this system, as it is currently operating, cannot be a suitable tool for facilitating the implementation of the Nagoya Protocol. This is because much of the information required to be certain about the way in which ABS was conducted and the obligations arising from it is missed. Thus, the ABSCH does not meet the objectives for which it was created, namely, being a platform for the exchange of information on ABS that enhances legal certainty, clarity and transparency on ABS process, and the monitoring the utilisation of the accessed resources.[168] It is believed that an effective and efficient tool for the exchange of ABS information will only

[167] FAO, The International Treaty on Plan Genetic Resources for Food and Agriculture <https://mls.planttreaty.org/itt/index.php?r=stats/pubStats> accessed 12 April 2018.

[168] More information on the objectives of the ABSCH available on: <https://absch.cbd.int/help/about> accessed 12 April 2018.

be possible if there is the obligation for users to disclose the necessary information to discover whether or not an obligation to share benefits has emerged and under what conditions. On this basis, and given that much of the ABS information is missing from the system, it becomes necessary to change the way it operates.

The above data is consistent with the conclusions reached in different studies about ABS implementation. From those studies, it can be affirmed that the practical implementation of ABS laws reveals the impossibility for individual countries to solve the main problems of ABS, as well as the difficulty of reaching international agreement on how to proceed regarding the application of these complicated aspects. The evident inability of the current international ABS system (CBD, FAO, and WHO) and IP system to resolve the problems resulting from the application of ABS regulations is perceived as the major obstacle for the distribution of benefits, and evidences the need for a response at the international level.

For this reason, this thesis argues that ABS implementation requires (i) an international understanding and agreement about the foundational aspects of ABS; (ii) the adoption of uniform international rules and proceedings for access, PIC, model agreements for MATs, and minimum percentages for the distribution of benefits; (iii) new utilisation of existing concepts, particularly, regarding access *ex-situ* and the public domain; and, (iv) an international dispute settlement body.

3. *Ex-situ* centres' progress towards compliance with ABS norms

This section deals with the participation of *ex-situ* centres in ABS transactions and seeks to offer a general understanding of their level of compliance with the obligations under such transactions. Regular claims about the alleged disruption to the ABS system caused by these *ex-situ* centres when they transfer biological samples to third parties (presumably without the sharing of benefits with the provider countries)[169] cast doubts on how much these centres have implemented ABS in their policies, how effective such implementation has been, the extent to which benefits have been distributed, and how many of these benefits have reached the countries of origin of the shared resources.

Whilst there is information on ABS, many issues related to benefit-sharing remain still unclear. In fact, one of the conclusions of the study conducted by Kate Davis and others is that:

> 'A major challenge for the botanic gardens community is to recognise, record and effectively communicate these benefits, to ensure that all benefit-sharing obligations are met (…) and to demonstrate to government authorities and ABS stakeholders the general and specific benefits that arise from botanic gardens' involvement in biodiversity conservation, research and sustainable use.'[170]

[169] See for example: CBD, Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, 'Analysis of the Claims of Unauthorised Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge' (2005) UNEP/CBD/WG-ABS/4/INF/6, 19-20

[170] Kate Davis and others, 'An Access and Benefit-Sharing Awareness Survey for Botanic Gardens: Are they prepared for the Nagoya Protocol?' (2015) 98 South African Journal of Botany 148, 156

Seemingly, the number, type and identity of beneficiaries of the benefits shared by *ex-situ* centres remain unclear. Nevertheless, despite the small amount of, and/or incomplete, information available regarding such benefits, this section will attempt to provide insights into these aspects of benefit sharing. To that end, the information obtained from the survey conducted by Davis and others is taken as a starting point.[171] Their data are supplemented by examples from other sources, such as Botanic Gardens Conservation International (BGCI) and the Royal Botanical Gardens at Kew.

The present analysis is relevant due to the fact that *ex-situ* centres' activities generate different reactions. For example, there is concern in the academic/scientific community that ABS might hamper scientific/non-commercial research.[172] In contrast, the reports of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing[173] and the Executive Secretary of the CBD[174] reveal the concern of some of the parties to the CBD that ABS is not designed for access *ex-situ* and that ABS obligations may be difficult to achieve in these cases. These two views reflect the main challenge for the implementation of ABS by *ex-situ* centres: how to continue contributing to scientific research without being accused of not complying with ABS.

3.1 Level of ABS implementation in *ex-situ* centres' collection policies

The majority of the gardens surveyed in Davis and others' study had plant collection policies in place. Thus, whilst US gardens were least likely to be addressing ABS in their policies, almost half of global-south and global-north gardens were addressing ABS, and municipal/provincial/state/federal and internationally-involved[175] gardens were significantly more likely to address ABS.[176] In terms of self-reported familiarity with ABS, the study found that gardens 'were less likely to be familiar with ABS than with the CBD and less familiar with the Nagoya Protocol than ABS generally,' with US gardens being the least familiar. The factors identified by the study, which would appear to determine gardens' familiarity with ABS, are: global-region reach, international involvement and full-time staff number.[177]

Overall, the gardens' most important initial sources for ABS information was the BGCI and other colleagues, while governments' CBD or ABS National Focal Points played a lesser

[171] ibid
[172] Matthias Buck and Clare Hamilton, 'The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity' (2011) 20 RECIEL 47, 59
[173] CBD, Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, 'Matrix on the Analysis of Gaps' (2005) UNEP/CBD/WG-ABS/4/3, 2-3; CBD, Ad hoc Open-Ended Working Group on Access and Benefit-Sharing, 'Analysis of Gaps in Existing National, Regional and International Legal and Other Instruments Relating to Access and Benefit-Sharing' (2007) UNEP/CBD/WG-ABS/5/3, 32-33
[174] CBD, Executive Secretary, 'Report of the Expert Meeting on Article 10 of the Nagoya Protocol on Access and Benefit-Sharing' (2013) UNEP/CBD/ABSEM-A10/1/3, 4-5
[175] Although this term is not explained by Davis and others in their article, it appears to refer to gardens' participation in international nets for the exchange of biological materials.
[176] Davis and others (n 170) 152.
[177] ibid, 151

role.[178] This suggests that, garden staff and users may feel satisfied that they are complying with ABS obligations when following the recommendations and/or policies developed in this regard by the BGCI, instead of consulting the CBD, the NP or the information provided by the ABS national authorities. This possibility justifies a review of the BGCI's ABS developments to see whether they are adequate.

The BGCI policies on ABS are composed of two voluntary approaches: 'The Principles on Access to Genetic Resources and Benefit-Sharing' (the principles) and 'The International Plant Exchange Network (IPEN)'. The principles 'provide a framework to help guide gardens and herbaria when developing their own individual policies', and the IPEN is a system aimed at complying with the CBD and the NP regulations. Further, IPEN was created for facilitating the exchange of living collections for non-commercial activities within a network of gardens that sign a Common Code of Conduct.[179] The usefulness of these tools cannot be denied. For example, the administrative burden could be reduced when all gardens develop their activities under the same rules. However, the fact that the BGCI policies on ABS are voluntary rather than mandatory may possibly create a false sense amongst garden staff and users that benefit-sharing is not an obligation derived from the CBD and the NP but something that depends more upon their good will, or where no damage is caused if no benefits are shared.

The BGCI present three case studies to demonstrate the success of ABS implementation.[180] The first one is the 'Documentation of Specimens and Samples' carried out by the Botanic Garden and Botanical Museum (BGBM) in Berlin. The existing information on this is limited to stating that BGBM activities are developed in line with EU regulations and international agreements on GR. However, mention of the national ABS laws of provider countries or to the benefits shared with them could not be found.[181]

'Implementing ABS at Oxford University' is the second example. In this case, reference is made to the non-monetary benefits shared with provider countries[182], the users' obligation to comply with benefit-sharing under the NP is set out, as well as the need for students taking part in overseas expeditions to address any ABS-related issues and obtain approval from the University Expedition Council. Clearly, thereby the University raises awareness amongst users of biological samples about the need to comply with ABS regulations, and it is a positive policy that the Oxford Botanic Garden and Arboretum (OBGA) refuses to supply materials when there

[178] ibid, 152

[179] <https://www.bgci.org/our-work/policy-and-advocacy/access-and-benefit-sharing/> accessed 09 December 2019.

[180] ibid

[181] <https://www.bgci.org/our-work/projects-and-case-studies/documentation-of-specimens-abs-and-nagoya/> accessed 09 December 2019.

[182] 'As well as the sharing of project-specific benefits agreed during planning, taxonomically verified specimens and digital images are sent back to the countries where plants were collected, duplicate material is stored in that country and, when only unicates are collected, they are sent back after identification. Holotypes are returned to the provider country's herbarium, although if there is no herbarium, holotypes and isotypes may be retained by the Oxford University Herbaria with an agreement that the material will be returned when a herbarium is established.'
<https://www.bgci.org/our-work/projects-and-case-studies/implementing-abs-at-oxford-university/> accessed 09 December 2019.

are doubts regarding future compliance with ABS.[183] However, because materials obtained from commercial suppliers are taken despite only requiring the supplier to 'sign a form declaring that the material concerned has been obtained in compliance with the Nagoya Protocol, to the best of their knowledge', it appears that the University is less strict when receiving samples.[184] It is of particular concern that the expression 'to the best of their knowledge' is used because through it the suppliers may seem authorised to say that they do not know whether the resources are of a legal origin but they think this is likely. A written declaration of this kind should not be accepted as suitable proof for legal access. A copy of a MAT or any other kind of permit delivered by the ABS national authority of the provider country would be better. The use of this declaration form may make it possible for the OBGA to receive biological samples that have not been acquired according to the ABS regulations of the country of origin. This may also contribute to decreased opportunities for provider countries to benefit from the use of their resources, because once a sample of dubious legal origin is incorporated into the OBGA, the same sample is by this act assumed to be of legal origin. Additionally, no information on the acquisition of samples from non-commercial suppliers was found. Thus, it is not clear whether all the samples they receive from these suppliers are from gardens that are members of the BGCI or not. This may suggest that gardens (and, perhaps, researchers in general) could assume that the sharing and acquisition of biological samples have different requisites and obligations, depending on whether they are obtained from commercial suppliers or non-commercial transactions (as the resources shared using the IPEN).

The final example is 'A Process for ABS-Compliant Fieldwork' implemented by the Jardín Botánico Universitario of the Benemérita Universidad Autónoma de Puebla (BUAP) in Mexico. The Botanical Garden of BUAP is a member of the Mexican Association of Botanic Gardens (AMJB in its Spanish acronym) and, consequently, implements the AMJB's ethical code of conduct and best practices. However, and within this frame, the information about this case is limited to describing the process of collecting and storing samples in the herbarium, but no information on ABS is provided.[185]

Davis and others' finding that gardens' most important initial sources for ABS information is the BGCI and other colleagues, rather than the CBD or ABS national authorities[186], seems to be confirmed by the information contained on the BGCI's webpage. This circumstance could generate problems of interpretation and application of the CBD and the NP, whilst also keeping *ex-situ* centres disconnected from the national and international ABS tools designed for the sharing of information on ABS related matters, such as the ABSCH of the CBD. The fact that only the MATs agreed to by *ex-situ* centres belonging to universities or research centres were reported to the ABSCH, as is shown in Table 4 in Section 2.2 of this chapter, seems to confirm this.

[183] ibid
[184] ibid
[185] <https://www.bgci.org/our-work/projects-and-case-studies/a-process-for-fieldwork/> accessed 09 December 2019.
[186] ibid, 152

There is little clarity about what the gardens' responsibility should be in terms of their role as intermediaries in the exchange of biological samples. Seemingly, the BGCI's position (taking it as an example) is that gardens have no responsibility for the way their recipients use the resources, and there is no need to take stronger measures to prevent resources of dubious legal origins entering their collections. On this, Article 15 CBD establishes that only the countries of origin or those authorised by them and that have acquired the GR in accordance with the Convention can be providers of GR. The key word in this situation is 'providers'. This is because, to be able to transfer samples of biological resources (which contain GR), providers must comply with the ABS regulations of the country of origin of the resources.

In this regard, although *ex-situ* centres act as providers of biological samples, they label themselves as 'suppliers', a term that does not exist in the CBD or the NP to describe or refer to the transfer of biological material to third parties by an agent other than an ABS national authority or a person authorised by it. Under the label of 'supplier', *ex-situ* centres seem to have created a different legal status, whereby they do not need to obtain PIC from the provider country to supply biological materials to third parties. This may reduce the chances for providing countries to know the use to which their GR is put, and, consequently, their chances to benefit from that use.

However, this does not mean that *ex-situ* centres are not committed to ABS compliance and benefit-sharing. In fact, as presented in the next section, they do share a broad range of benefits, some of which appear to be directed towards provider countries. Nonetheless, the responsibility of *ex-situ* centres in ABS transactions is a topic that needs to be studied, developed and clarified by academia and policy makers, since it is of similar importance to other IP issues, such as the responsibility of internet service providers (ISP) with regard to the legality of the content circulating through their systems. It could be argued that only if *ex-situ* centres check that the materials they hold were acquired according to the CBD, could they be considered safe harbours for sharing GR. In the same vein, it should be determined whether a declaration from a supplier attesting to the legal origin of the biological samples would be sufficient for *ex-situ* centres in order to receive samples in their collections or whether proof of legal access is also necessary.

In addition, it is remarkable that one main conclusion of the survey is 'that many respondents are not yet familiar with access and benefit-sharing or the Nagoya Protocol'.[187] This may indicate that *ex-situ* centres are sharing benefits without having a strong level of institutional knowledge/expertise in ABS. Moreover, it might suggest that such centres have had benefit-sharing systems in place for many years, possibly even before the CBD. The fact that they have implemented benefit-sharing systems without knowing much about ABS suggests that the way in which some *ex-situ* centres conduct benefit-sharing does not necessarily derive from the application of the CBD or the NP, but from their experience and previous practices. The fact that *ex-situ* centres located in the US, a non-party to the CBD (and the country least familiar with ABS)[188], conduct benefit-sharing reinforces this idea. For these

[187] Davis and others (n 170) 148.
[188] ibid, 151

reasons, a proposal for a mechanism to achieve ABS at an international level should incorporate the practices already implemented by *ex-situ* centres.

3.2 Amount and type of benefits distributed

The first finding to be noted is that the survey reveals the existence of a reasonably wide range of benefits that have in fact been shared, many of which (joint publications, exchange of knowledge and staff, and provision of educational materials and of technical support) may possibly be with countries of origin, while some (especially reintroduction/habitat restoration, joint expeditions, and access to and publication of research results in provider country) seem particularly likely to be directed to countries of origin.[189]

Although the survey states that benefit-sharing is not analysed in depth, it contains some statistical data.[190] Among other things, it indicates that most respondents reported sharing benefits (86%), with the highest proportion of gardens having international involvement (97%) and being located in the global north (92%), followed by non-internationally-involved gardens (88%), gardens in the global south (84%) and in the US (81%).[191] The most commonly-shared benefits were knowledge (horticultural and taxonomic knowledge).[192] Joint expeditions and taxonomic knowledge were commonly-shared benefits for internationally-involved gardens, while the oposite was true for non-internationally-involved gardens.[193] Internationally-involved and gardens in the south also reported more research-related benefits, such as joint publications, local publication and access to results.[194] Table 9 of the survey reveals that other benefits have been shared, such as the exchange of garden staff, education materials, technical support, reintroduction/habitat restoration, publication of results in provider country, access to results in provider country, and direct financial support, although to a lesser degree.[195]

3.3 Amount and type of benefits shared with the countries of origin

From the available information it is very difficult to establish the amount and type of benefits that *ex-situ* centres share with countries of origin. However, from the same information, it could appears that the distribution of benefits may very often occur between *ex-situ* centres and their users (most of which apparently are other *ex-situ* centres) rather than between *ex-situ* centres and countries of origin.

The first indication for this deduction is found in the results of the survey conducted by Davis and others, in which it is shown that *ex-situ* centres 'are often intermediaries in networks

[189] ibid, 154
[190] ibid, 153
[191] ibid
[192] ibid
[193] ibid
[194] ibid, 153-154
[195] ibid, 154

of use of plant biodiversity'[196] where they most commonly supply materials to other botanic/public gardens and universities/research institutions.[197] As previously noted, it is possible that gardens usually obtain their samples from other gardens and share them with other gardens, i.e. access *in-situ* is the exception, meaning that on only a few occasions benefits are shared with countries of origin.

In addition, the majority of gardens surveyed do not use MTAs, with only 43% doing so. Where used, this accounts for 59% of global-south gardens, 56% of global-north gardens, and 24% of US gardens. Moreover, internationally-involved gardens are more likely to use MTAs than non-internationally-involved gardens. Where MATs are employed, a majority of gardens (60%, which is equivalent to the 25.8% of all surveyed gardens) link permit/agreement terms to their records of sharing activities.[198] This may mean that the fact that gardens have ABS policies in place does not guarantee that gardens are always or fully implementing them. Also, MATs contain the agreements on access and benefit-sharing, for which, they are essential to check that ABS commitments have been fulfilled. Thus, the absence of MATs within the 57% of the surveyed gardens, with only 25.8% of them recording sharing activities, seems to indicate that in all other cases no benefits have been shared or that the sharing of benefits may be happening under standard rules/uses of the collection providing the resource, instead of under mutual agreements between the parties involved.

An additional perspective on MATs can be found on the IPEN website, where two instruments are suggested: the 'IPEN Mutually Agreed Terms' and the 'Material Transfer Agreement Template'.[199] The first directs readers towards guidelines for the development of a 'basic agreement on access and benefit-sharing for academic research', as proposed by Susette Biber-Klemm and others[200], while the second is a ready-to-use MAT. In other words, the first provides guidance to gardens for the creation of their own MATs, while the second is a ready-to-use instrument. This provision suggests that MAT documents could be used to a greater extent by gardens. Unfortunately, there is no information available on the number and characteristics of the MATs agreed in the context of IPEN gardens.

Nevertheless, it is worth drawing attention to the fact that the instructions given by Biber-Klemm and others meet the criteria contained in the CBD, while the MAT template created by the IPEN is not so reflective. Regarding the use of the word 'supplier', previously discussed, the IPEN format seems to relieve gardens of ABS liability in terms of absence of

[196] ibid, 148

[197] ibid 152. The next most frequent category of third party supply was plant sales to the public, with fewer gardens supplying other commercial sectors. More internationally-involved gardens supply material than do non-internationally-involved gardens, a higher proportion of US gardens and global-south gardens supply plants to the public via plant sales compared with global north gardens, and internationally-involved gardens supply material more frequently via plant sales than do non-internationally-involved gardens.

[198] ibid, 153

[199] <https://www.bgci.org/resources/bgci-tools-and-resources/international-plant-exchange-network-resources/> accessed 09 December 2019.

[200] Susette Biber-Klemm and others, 'Agreement on Access and Benefit-sharing for Academic Research: A toolbox for drafting Mutually Agreed Terms for access to Genetic Resources and to Associated Traditional Knowledge and Benefit-sharing' (Swiss Academies of Arts and Sciences, Swiss Academies Reports 11(3) 2016), 36-42

responsibility by considering them as 'suppliers'. In this case, the responsibility for ensuring benefit-sharing with the country of origin and obtaining PIC in the events of commercial use or transfer to third parties for commercial use is passed on to the recipient. However, due to Article 15 of the CBD establishes that *ex-situ* centres, when acting as suppliers of GR, have to access the supplied resources according to the national law of the country of origin; it might be inconvenient to set out a general rule (in this case, a ready-to-use MAT) to be applied on every occasion for a situation that could be regulated differently by countries of origin. This could create the perception for gardens that compliance with ABS means compliance with the IPEN rules rather than with the ABS national laws of countries of origin and, therefore, could generate claims of alleged non-compliance with those national laws.

Additionally, because the majority of the gardens surveyed track the arrival of materials (52%), while transfer to third parties was much less likely to be tracked (36% did not; 12% did not know)[201], it seems that gardens are less interested in keeping information about the users of the samples they supply, which is also an essential aspect of benefit-sharing reclamations, either by them or by a country of origin.

Although both the survey and the website of the BGCI indicate that some benefits have been shared, it is not clear what kind of benefits or in what amount these have been directed towards countries of origin. In particular, on the BGCI's website it is confirmed that the use of plant resources in research and development is promoted in compliance with national and international ABS laws and policies. To do this, affiliated gardens and research centres have developed a range of ABS sectorial policy tools, including codes of conduct and best practice, which recommend obtaining PIC from providers and ILCs before accessing their plant resources and TK, data management systems, and awareness-raising.[202] This seems to be confirmed by the survey, in which most respondents reported having shared benefits (86%).[203] The BGCI's website also states that although '[I]n many cases research is non-commercial and benefits are non-monetary, (…) non-commercial research can also involve the sharing of monetary benefits.'[204] Nevertheless, the survey also confirms that the benefit largely shared is information while monetary benefits are less common.[205]

The 'Bilateral and Global Benefit Sharing at the Royal Botanic Gardens, Kew' and the 'Good practices for working with the Mexican Association of Botanic Gardens (AMJB in its Spanish acronym)' are presented by the BGCI as examples of successful cases of benefit-sharing.[206] Because of this, it would be reasonable to expect to find, through the links provided in the website, a description of the type and amount of monetary and non-monetary benefits shared in those cases. However, the links lead to other websites with detailed information

[201] Davis and others (n 170), 152-153

[202] <https://www.bgci.org/our-work/policy-and-advocacy/access-and-benefit-sharing/implementing-access-and-benefit-sharing/> accessed 09 December 2019.

[203] Davis and others (n 170), 153

[204] <https://www.bgci.org/our-work/policy-and-advocacy/access-and-benefit-sharing/implementing-access-and-benefit-sharing/> accessed 09 December 2019.

[205] Davis and others (n 170), 153

[206] <https://www.bgci.org/our-work/projects-and-case-studies/bilateral-and-global-benefit-sharing/> accessed 09 December 2019.

about the ABS policies and practices that Kew and the AMJB use. For example, Kew uses ABS agreements (Memoranda of Collaboration and Access and Benefit Sharing Agreements), where benefits typically include: research results, specimen data and images, copies of publications, training and funding opportunities, and joint publications or authorship,[207] while the AMJB has developed a code of conduct for working with ILCs.[208] The code includes useful information about the way research projects should be formulated and implemented, and mentions, as examples of non-monetary benefits: the development of fieldwork, consisting of workshops aimed at diverse groups of the community and covering areas such as education, horticulture, ethnobotanical approaches; inviting the ILCs to visit the botanic garden to observe the results of the project in which they have participated; and planning guided visits to the botanic garden. Also recommended is the sharing of publications generated by the project; developing a report to deliver to the authorities, including data about the participants; including recommendations for possible projects for the benefit of the ILCs; ensuring that the wording is appropriate to the type of recipient; and linking the community with potential markets.[209]

Despite these recommendations, no additional information is given on the BGCI,[210] Kew,[211] and AMJB[212] websites showing data regarding the benefits actually shared. Thus, the level of compliance of Kew and the AMJB with provider countries' ABS laws and particular obligations derived from MATs remains unknown. Furthermore, the type and amount of benefits actually shared with provider countries is also uncertain. However, it should be acknowledged that this does not mean that they have not done anything to comply with ABS, or that this conclusion can be drafted.

Another possible indication that the benefits from access *ex-situ* might be mostly shared between *ex-situ* centres is the number of resources accessed vs the number of resources shared in the MLS of the FAO. In 2018, samples provided by 41 countries were transferred to recipients located in another 179 countries, which permitted access 3.25 million times.[213] Given that the MLS is a system designed to facilitate the sharing of samples by *ex-situ*

[207] ibid

[208] <https://www.bgci.org/our-work/projects-and-case-studies/good-practices-for-working-with-communities/> accessed 09 December 2019.

[209] ibid

[210] <https://www.bgci.org/our-work/policy-and-advocacy/access-and-benefit-sharing/implementing-access-and-benefit-sharing/> accessed 09 December 2019.

[211] See for example:

- 'Conservation, sustainable use and benefit sharing' <https://www.kew.org/about-us/reports-and-policies/conservation-and-sustainable-use> accessed 09 December 2019.
- https://www.kew.org/read-and-watch/nagoya-protocol-closer-to-fruition> accessed 09 December 2019.
- https://www.kew.org/read-and-watch/kew-and-convention-on-biological-diversity> accessed 09 December 2019.
- 'Policy on Access to Genetic Resources and Benefit-Sharing' <https://www.kew.org/sites/default/files/2019-02/genertic%20resources%20policy.pdf> accessed 09 December 2019.

[212] <http://www.concyteq.edu.mx/amjb/index.html> accessed 09 December 2019.

[213] FAO, The International Treaty on Plan Genetic Resources for Food and Agriculture <https://mls.planttreaty.org/itt/index.php?r=stats/pubStats> accessed 12 April 2018.

centres, these figures may suggest that some resources went from *ex-situ* centres located in 41 countries of origin to *ex-situ* centres located in 179, which are not countries of origin, and that shared 3.25 million times these samples with other *ex-situ* centres, which possibly are not in all cases located in countries of origin.

Whilst it is not possible to say to what extent the countries of origin benefit from the use of their resources, based on this information, it seems highly probably that *ex-situ* centres are more likely to acquire biological samples from other *ex-situ* centres rather than from countries of origin. This being the case, it may be difficult to conclude that countries of origin receive a portion of the benefits shared by *ex-situ* centres after accessing GR from another *ex-situ* centre, when neither one is the country of origin of the shared GR. If this is so, one of the major challenges for *ex-situ* centres and countries of origin is to work together to find a way in which the latter can benefit from the use of their resources, even in cases where these are shared between *ex-situ* centres which are not countries of origin.

In the same vein, the little existing information on PIC, MATs and benefit-sharing seems remarkable. This fact is also noted by Davis and others, who identify the need for the botanic garden community to 'record and effectively communicate these benefits, to ensure that all benefit-sharing obligations are met (as set out in permits/agreements with providers)'.[214] Adding to this, it could be said that *ex-situ* centres should provide information to the ABSCH and national facilities created for the sharing of information on ABS related matters. They should also engage with their ABS national authorities to avoid different interpretations, approaches, and/or implementation of the CBD and the NP, and to develop their ABS policies in coordination with those authorities.

Despite these flaws, the developments of *ex-situ* centres in the incorporation of ABS rules in their policies and procedures is evident, although the available information leaves many gaps in regard to their level of compliance with ABS.

4. Conclusions

On the occasion of the entry into force of the CBD, ABS obligations were introduced in the national or regional laws of some Parties to the Convention. An overview of the number of legal measures adopted on ABS makes it quite clear that the level of implementation is low (139 Members of the CBD (71%) have not yet implemented any such measure) and usually incomplete (for example, many legal developments are limited to repeating the content of the CBD and the Protocol and to stating that its clauses will be regulated in detail in further regulations, which have not yet been developed).

Such measures often reflect some of the characteristics of the country implementing the law, i.e., their legal and administrative structure, priorities regarding ABS (facilitated access or protection of GR and TK), and their reality (those countries that do not have ILCs have no

[214] Davis and others (n 170), 156

measures on access to TK, although they affirm the need to distribute the benefits derived from its use).

The broad concepts and unclear obligations contained in the CBD bring the logical consequence of the absence of a harmonised approach to ABS. This way, ABS local developments exhibit multiple interpretations of the concepts of the CBD and diverse forms to conduct ABS processes (as described in Section 2.1.1 of this chapter).

Differences in ABS laws seem to be connected with the potential role of countries as providers or users in ABS transactions. This way, it can be observed that provider countries' provisions are mainly directed towards clarifying the elements outlining the ABS scope. Thus, the concepts of GR, genetic heritage, TK, non-identifiable TK, by-products, derivatives, biochemical elements, and access, among other things, are provided. For its part, user countries appear to be more concerned about determining when an obligation to distribute benefits exist.

Generally speaking, it can be said that national and regional ABS developments are relatively clear regarding their own scope, concepts, procedures, obligations, and sanctions resulting from non-compliance with ABS obligations.

A more detailed observation of these aspects led to the view of some common and non-common elements. For example, all countries have an ABS competent national authority. A written authorisation from the competent authority is required for accessing GR and TK. However, PIC as a pre-requisite for access to GR is only an obligation in the CAN, Costa Rica, and the African Union. To access TK, PIC is only referred to in those countries which have ILCs within their frontiers, being a pre-requisite for access in Brazil, the CAN, Costa Rica, and the African Union. Another common element is the obligation to concede access upon a written agreement reached between the parties. This instrument is often referred to as 'the access contract' and some models and guidance for its elaboration have been established within national legislations.

Prohibitions are also clear: they can utilise the prohibition to use the resources in different ways than those authorised; the prohibition to collect resources outside the authorised lands; the prohibition to collect more than the resources authorised; the prohibition to share samples of GR, their related information and associated TK; and the prohibition to obtain IPRs or the obligation to share such rights with the provider.

Controlling activities are mainly related to the development of collaborative scientific research and the obligation to disclose the origin of the resource in scientific publications; while monitoring is commonly limited to the request of information regarding to the activities developed within the authorisations made under MATs.

Regarding the use of TK, provider countries' laws show a clear trend towards the recognition and protection of ILCs' rights over their TK. In this regard, these norms provide for: (i) PIC as a requisite for accessing TK; (ii) the right of ILCs to refuse access and to withdraw PIC; (iii) the obligation to respect customary laws and protocols of ILCs, (iv) the obligation to distribute the benefits derived from the use of TK, even in cases where such knowledge is in

the public domain; and (v) clear instructions regarding the way benefits must be distributed with the ILCs, even when dealing with particular and complicated cases, such as shared TK.

Although all measures share the common elements of ABS in the CBD and the Protocol, national laws exhibit different levels of development and detail. For example, a number of countries have different rules for access to GR and TK depending on the sector to which the applicant belongs (e.g., a researcher based in a university or a researcher from a company); the intended use of the resource (commercial or non-commercial); the type of resource (GR or TK); and the number of resources to be accessed (single access contract or multiple framework contract). These agreements usually include provisions for compliance, such as fines, seizure of samples, and revocation or cancellation of the access permits (MATs).

Additionally, some solutions for the non-regulated aspects of ABS have been implemented through national and regional developments, on access *ex-situ*, the public domain, and shared TK:

i. Although some rules have been established on access *ex-situ* they do not fulfil the purpose of distributing the benefits. Under the EU, access *ex-situ* is considered outside ABS because GR *ex-situ* is assumed to be in the public domain and access *ex-situ* is presumably be conducted with due diligence. In other countries, access *ex-situ* is allowed for conducting non-commercial research and the sharing of samples and acquisition of IPRs over developments based on the accessed resources is forbidden. However, no rules indicate how to proceed for a change of the resource's use from non-commercial to commercial.
ii. In Costa Rica, all GR and TK are considered to be in the public domain, but the State retains the right to authorise their use and benefit from it. In Brazil, the use of all TK generates the obligation to distribute benefits. Publications, databases, inventories, and any other way of disclosing TK is used as a proof of the TK's Brazilian provenance and, as such, as proof that a distribution of benefits is due. In Panama and Peru, the obligation to distribute the benefits derived from the use of TK in the public domain exists, as long as they are the country of origin of such TK. The Dominican Republic does not expressly stipulate that TK in the public domain is in the ABS scope, but declares that TK can be found in oral and written forms.
iii. In Brazil, the benefits arising out of shared TK must be distributed among all ILCs to whom such TK belongs. The community granting PIC has the right to benefit in the terms established in the MAT. Part of the benefits must be paid into a national fund in charge of distributing them between the rest of communities to whom the accessed TK belongs. In Bhutan, all ILCs holding the same TK have the right to negotiate MATs and to benefit from its use. Ethiopia holds that the distribution of benefits should be done according to the ILC's relative contribution to the conservation of the accessed GR and/or TK.

As regards MATs, although the data might be small in number (134), some provisional conclusions can be drawn from their analysis:

i. It is not possible to affirm that legal certainty and detailed processes can produce better results in terms of the production of MATs. For example, Peru has a complete legislative response and one single authority ruling ABS, and IPRs reported only one MAT, whilst Mexico who has no ABS law and signed three MATs.
ii. It cannot be affirmed that the small number of MATs is caused by a lack of interest of the industry and private sector in the utilisation of GR and TK. On the one hand, as statistically demonstrated in Section 4.3 of Chapter 5, the number of patents and patent applications using GR and TK has shown a sustained growth. On the other hand, the number of MATs subscribed with the private sector represent 35% of the total (see Tables 7 and 8). This trend seems to be confirmed by the number of accessions to GR happening through the MLS of FAO (Section 2.2 of this chapter).

Implementation of ABS appears almost impossible to achieve through individual actions of the Parties to the CBD. In addition, the evident inability of the current international ABS system, in conjunction with the IP system, evidences the need for a response at the international level.

This response can be achieved if ABS implementation gains a certain level of international reach, as well as international agreement on (i) the foundational aspects of ABS; (ii) uniform international rules and proceedings for access, PIC, model agreements for MATs, and minimum percentages for the distribution of benefits; (iii) new utilisation of existing concepts, particularly, regarding access *ex-situ* and the public domain; and, (iv) an international dispute settlement body.

In conclusion, based on the available information, it could be inferred that, despite the extent of benefits shared by *ex-situ* centres, the majority of ABS transactions are between centres. Therefore, is not possible to establish which of these benefits are actually going back to the countries of origin. Consequently, it is uncertain whether *ex-situ* centres are fully complying with ABS regulations.

CHAPTER 3. The design of the Access and Benefit-Sharing (ABS) System of the Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP)

1. Introduction

This chapter analyses the way in which the ABS system has been designed. It first describes how ABS should work according to the CBD, and then shows the way in which the NP clarifies the content of the CBD. From this explanation, the fact that the NP does not modify or add new obligations on ABS to those already prescribed in the CBD begins to be clear. Finally, those aspects over which the Parties to the CBD could not reach an agreement, and those that were not discussed during the negotiations of the NP are presented. This information is relevant because it presents a more complete vision of ABS.

The chapter concludes by suggesting that the problems experienced by the countries in the application of ABS laws could be due to the absence of agreement on sensible aspects, such as access to GR *ex-situ* and the public domain.

2. ABS in the CBD

2.1 The legal basis of ABS

The CBD is a multilateral agreement aiming to address all aspects of biodiversity. It has three major objectives:

i. The conservation of biological diversity;
ii. The sustainable use of biodiversity; and,
iii. The fair and equitable sharing of the benefits arising out of the utilisation of genetic resources (GR).

These objectives are based on the premise that protection and preservation of natural resources is a common concern of mankind and that an appropriate sharing of the benefits (scientific knowledge, technologies and economic value) derived from its use could help with the *in-situ* conservation of biodiversity.

To achieve these objectives, the CBD recognises the sovereign rights of the countries over their natural resources, which has three main effects. First, each country has the authority to determine the access and utilisation of their biodiversity. Second, each is responsible for the loss or reduction of biodiversity within their territories. Third, each has the right to benefit from the utilisation of their biodiversity. The first two constitute the specific allocation of both rights and obligations regarding the preservation and sustainable use of biodiversity, while the third is a consequence of the exercise of sovereign rights.

The exercise of sovereign rights over biodiversity is the legal basis of ABS. Based on this, the CBD recognises the right of each country to benefit from the use of their GR, regardless of whether they have been accessed in *in-situ* or *ex-situ* conditions. Access can only be granted by the country of origin, which is understood as the country where the GR is found *in-situ* even in cases when the resource is stored in an *ex-situ* centre. For this reason, after the CBD entered into force, *ex-situ* centres are required to follow the ABS rules for the activities of collecting and storing GR. Additionally, they need the authorisation of the country of origin before they share samples of GR. Accordingly, the countries of origin and *ex-situ* centres could be providers of GR. This refers to the national/bilateral approach explained in Section 1.2.3 of Chapter 1.

2.2 The ABS Process of the CBD

The process of ABS, as established in Article 15 of the CBD,[1] requires that users of GR ask for permission to providers before they physically access the resources. Once such authorisation has been given, users and providers have to reach an agreement on the conditions for access, the permitted uses, and the distribution of benefits. The first step is known as seeking and obtaining 'prior informed consent' (PIC), and the resulting agreement is known as the 'mutually agreed terms' (MATs). In this way, access is conditional on PIC, and benefit-sharing has to be done according to MATs.

Other elements complementing ABS include:

i. The states' right to determine access to GR through their national law;

[1] Convention on Biological Diversity (adopted 05 June 1992, entered into force 29 December 1993) 1760 UNTS 79 (CBD).

'Article 15. Access to Genetic Resources:

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.'

ii. Their obligation to create favourable conditions for accessing GR for environmentally-sound uses;
iii. The exclusive right of countries of origin to authorise access to their GR *in-situ* and *ex-situ*;
iv. The obligation for *ex-situ* centres to concede access to GR only when these resources have been acquired in accordance with the CBD; and
v. To distribute the monetary and non-monetary benefits derived from the use of GR in a fair and equitable way.

Despite the apparent simplicity of this process, problems in its implementation have existed since its introduction in the CBD. That is why the parties to the CBD have continued to search for a better way to put ABS into practice. As a result, the NP was agreed upon in 2010. Its practical implications for ABS are explained below.

3. ABS in the Nagoya Protocol to the CBD

The NP is a supplementary agreement to the CBD containing legal obligations on ABS. After more than six years of negotiations, it was adopted in the Japanese city of Nagoya in 2010 at the tenth meeting of the Conference of the Parties (COP) of the CBD. From a legal point of view, the CBD and any protocols subsequently concluded are separate instruments. This means that the parties to the CBD have no obligation to become parties to any of its protocols[2] and, therefore, are only bound by the terms of the Convention. The logical consequence of this is that non-members to the NP have no obligation to comply with any new obligations on ABS that are introduced. However, as further demonstrated in this chapter, the NP does not create new ABS obligations, it rather makes them more precise.

The NP's critical importance is that it seeks to provide a legally-binding framework for ABS. For Robinson, the reproduction of the CBD's principles and rules in the text of the NP represents a step forward in the achievement of benefit-sharing.[3] This is relevant because the CBD is a hard law instrument that operates in the manner of an aspirational, policy-oriented soft law;[4] because its provisions are expressed as overall goals and policies rather than as concrete obligations.[5] Given this, doubts have been raised regarding the effectiveness of the CBD in achieving ABS. For example, Raustiala notes that the vague commitments and

[2] This can be clearly seen when comparing the number of Members of the CBD (196) with the number of Members of the Nagoya Protocol (104). CBD, 'List of Parties' <https://www.cbd.int/information/parties.shtml#tab=2> accessed 04 April 2018

[3] Daniel Robinson, 'Nagoya Protocol in the Spotlight with CBD Meet Ahead' (2014) 8 BioRes 4, 6.

[4] In opinion of Birnie and Boyle the soft nature of the CBD is the result of a difficult process of negotiation, in which the countries were not disposed to accept more precise commitments in a Convention but pleased to clarify its details through national laws.
Patricia Birnie, Alan Boyle and Katherine Redgwell, International Law & the Environment, (OUP) (2009, 3rd edn), 617.

[5] Stuart Harrop and Diana Pritchard, 'A Hard Instrument Goes Soft: The Implications of the Convention on Biological Diversity's Current Trajectory' (2011) Global Environmental Change 474, 476.

ambiguous phrases[6] of the CBD facilitates the avoidance of its obligations by its Parties.[7] For that reason, it was expected that the NP could give better binding power to the CBD clauses on ABS. However, as explained below, the countries also experienced difficulties in reaching agreement on sensitive issues during the negotiations of the Protocol, some of them could not be agreed upon and, therefore, were not incorporated in its final text.

In order to identify the possible flaws in the design of the CBD and the NP which may be hindering ABS implementation, the following sections present: (i) the ways in which the NP attempts to provide clarity and achieve compliance with ABS, and (ii) the issues that were not addressed by the CBD and Protocol. The latter is divided into non-agreed and non-discussed issues. They have been incorporated in this analysis because a better understanding of ABS should consider aspects that were both included and not included in the system.

3.1 Clarifications provided by the Nagoya Protocol to the ABS process of the CBD

The NP seeks to specify the legally-binding framework of ABS through reference to Articles 1, 15, 16 and 19 of the CBD. In doing so, it:

i. Reaffirms the sovereign rights of states over their natural resources;
ii. Recognises that the fair and equitable sharing of the economic value of biodiversity are key incentives for the conservation of biodiversity;
iii. Recognises the importance of providing legal certainty with respect to ABS;
iv. Recognises the interdependence of all countries with regard to GR for food and agriculture as well as the importance of such resources for the mitigation of climate change;
v. Acknowledges the ongoing work in other international forums relating to ABS (FAO and WHO);
vi. Recognises that international instruments related to ABS should be mutually supportive with a view to achieving the objectives of the CBD;
vii. Recognises the interrelationship between GR and TK, and the importance of this knowledge for the conservation of biodiversity, the sustainable use of its components, and the sustainable livelihoods of these communities;
viii. Recognises that it is the right of indigenous and local communities (ILCs) to identify the rightful holders of their TK within their communities; and

[6] Some of the terms used in the CBD's preamble recitals and its substantive articles are for example 'as possible', 'practicable in accordance with particular conditions and capabilities', 'taking into account special needs', 'likely to', 'grave and imminent', 'significant', and the inclusion of weak words accompanying its obligations, for instance 'endeavour', 'encourage', 'promote' and 'minimise'. Their adoption has made it difficult to determine the scope of the obligations and commitments over the State Parties of the CBD, and consequently has facilitated their unfulfillment.

[7] Kal Raustiala, 'Domestic Institutions and International Regulatory Cooperation: Comparative Responses to the Convention on Biological Diversity' (1997) 4 World Politics 482, 491-492.

ix. Sets out that nothing in its text shall be construed as diminishing or removing the rights of ILCs.

As previously stated, the NP does not modify or add new elements to ABS as established in the CBD. Therefore, as does the Convention, it stipulates that access to GR is conditional on PIC from the Party providing GR (Articles 6.1 and 6.2), and establishes that, unless otherwise determined by a national law of that Party, providers of GR could be: (i) the country of origin of the resource; (ii) a Party that has acquired the GR in accordance with the Convention (Article 6.1); and (iii) ILCs respecting the GR located within their territories, provided this right has been recognised in their countries of origin (Article 6.2).

Additionally, Article 3 NP clarifies that TK is within the ABS scope. In this regard it establishes that access to TK is conditioned to the PIC conceded by the concerned ILCs, and to distribute the benefits derived from its use with these communities (Article 7). Initial doubts about the obligation to distribute the benefits derived from the use of TK seem to be generated by the fact that, although this aspect was incorporated in the Preamble and Article 8j of the CBD, it is not part of Article 15 regulating ABS. Thus, the clarification in the NP that TK is in the ABS scope could be perceived as a step forward in the protection of ILCs' rights. Nonetheless, as evidenced in the laws reviewed in the previous chapter, only few countries have included the right of ILCs to grant PIC and/or have specified the percentage of monetary benefits they should receive.

As does the CBD, the NP provides that the fair and equitable sharing of the benefits is an obligation originating from the utilisation of GR and TK. However, it clarifies that 'utilisation of GR' means (i) research and development on the genetic/or biochemical composition of GR, including the application of biotechnology (Article 2c); (ii) subsequent applications of such research and development; and (iii) the commercialisation of these resources (Article 5.1). Although the NP does not explain what the utilisation of TK is, given that a distribution of benefits derived from the use of TK is only possible when such knowledge is associated with a GR, it can be concluded that it involves the use of a TK in research activities, applications, and commercialisation. The implication of these concepts on ABS processes is explained in the next chapter.

Finally, both the CBD and the NP require that the conditions for access, utilisation, and the distribution of benefits should be upon MATs (Articles 5.5, 6 and 7).

In addition to what has been said, the NP also:

i. Suggests the creation of a global multilateral benefit-sharing mechanism (GMBSM) for accessing resources in transboundary situations and when it is not possible to grant or obtain PIC (Article 10); and
ii. Proposes a set of instruments to support ABS compliance, including mechanisms for tracking and monitoring the resources through the implementation of

checkpoints and/or the use of an internationally-recognised certificate of compliance and the inclusion of reporting obligations in MATs (Article 17).

Given the importance of those aspects, each of them is explained as follows.

3.1.1 Traditional knowledge-related developments

The need to protect TK and to share the benefits derived from its utilisation with the ILCs is expressed in the Preamble and Article 8j CBD. In the absence of any mention of TK in Article 15 CBD establishing ABS, Article 3 NP clarifies that it is in the ABS scope.

However, the right of ILCs to benefit from the use of their TK seems to be conditional upon the recognition of this right in national laws. In other words, the decision to protect TK and to recognise the right of ILCs to benefit from its use is taken, in practice, by each state through the implementation of national laws. Unfortunately, this does not seem to be a priority for either the governments of provider or user countries of TK. This is because, as observed in the data presented in Chapter 2, few countries have developed specific regulations on TK and ILCs' rights, and only three countries have integrated customary laws and/or protocols in their ABS proceedings (Brazil, Kenya, and Panama). For this reason, as suggested in Section 1.2.2.a of Chapter 1, the design of any ABS mechanisms for TK should not be subjected to TK protection or the recognition of IPRs over this knowledge.

3.1.2 ILCs-related developments

Besides clarifying that TK is within the scope of ABS, the NP mentions a set of rights that could positively contribute to ensuring that ILCs can benefit from the use of their resources (GR and TK). For example, it explains that the ILCs can grant PIC for the access to their TK and GR when located in their territories (Articles 6.2 and 7). The CBD, containing general rules, was silent in this regard. For that reason, before the NP, it was not clear whether PIC could be granted by the ILCs or by the state in their behalf. Nonetheless, attention should be given to the way in which this right has been recognised. On one hand, users can access the resources by obtaining PIC or the 'approval' of ILCs. As explained in the next chapter, although PIC involves the approval of providers regarding the access to their resources, the distinctive characteristics of PIC make of it something more than just an approval. Thus, for the country Members of the ILO Convention 169, an approval obtained in a different way than it is prescribed for PIC would not be acceptable.

On the other hand, ILCs can grant PIC for the TK they hold and the GR which is found in their territories as long as they have the established right to do so. Regarding TK, the use of the word 'hold' could be problematic. One possible interpretation could be that the ILCs can only benefit from the TK over which some form of control is retained. Another possibility is that ILCs could benefit from the use of the TK they hold, irrespective of whether or not it is in

the public domain. These opposite interpretations have been found in the laws analysed in the previous chapter. In general, the countries were silent on this aspect and in only four of them there is the need to conduct an ABS process when TK and/or GR in the public domain have been used (Brazil, Costa Rica, Panama, and Peru). The consequence of choosing one of these two interpretations is that the ILCs can benefit from the use of a wide range of TK (when it is in the public domain)[8] or a small amount of it (over which control is attained).

As evidenced in the official records of the NP negotiations, it seems that this is one of the aspects over which the countries would not be able to reach an agreement or a solution beyond what they have already established through their national or regional laws.[9] Additionally, as noted by Buck and Hamilton, terms such as 'traditional knowledge associated with genetic resources', 'indigenous and local communities', and 'held' are not defined in the NP, the CBD, or other international legal instruments.[10] For that reason, it could be problematic to establish when a TK is associated with a GR, or when a TK is held by an ILC. This could explain to some extent, why the different approaches regarding TK in the public domain have been found in the laws revised.

Another clarification made by the NP is that ILCs can be the beneficiaries of the use of GR and TK (Article 5.2 and 5.5).

Finally, the Protocol indicates that access to TK is not only conditional on PIC of the ILCs concerned, but also that such a process has to take into consideration their customary laws, protocols, and procedures (Article 12.1). To do this, states are required to establish mechanisms to inform potential users about their obligations relating to TK (Article 12.2), and to support ILCs in the development of their protocols, minimum requirements for MATs, and model contractual clauses for ABS (Article 12.3). This aspect is fundamental to the protection of ILCs' rights. However, it also presents a big challenge for the implementation of ABS because more laws on ABS will increase the fragmentation and complexity of the system and could result in higher transactional costs and lower efficiency.

[8] A large amount of TK is considered to be in the public domain because it has been made available to the public, by any means. Initially this was caused by colonisation, and later by many other reasons. In the words of Michael Brown: 'In the late 1980s, ownership of knowledge and artistic creations traceable to the world's indigenous societies emerged, seemingly out of nowhere, as a major social issue. Before then, museum curators, archivists, and anthropologists had rarely worried about whether the information they collected and managed should be treated as someone else's property.'
Michael F Brown, *Who Owns Native Culture?* (HUP 2003), ix.

[9] The issue of publicly available TK was discussed during the negotiations of the Protocol (Art. 9.5 of the Protocol's Draft). It was particularly considered the need that users enter into a benefit-sharing process with the rightful holders of TK when the knowledge is obtained from a source other than a traditional community.
Stefan Jungcurt and others, 'Summary of the Resumed Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 10-16 July 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 19 July 2010, vol 9, n 527), 9, 15; Jungcurt and others, 'Summary of the Tenth Conference of the Parties to the Convention on Biological Diversity: 18-29 October 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 1 November 2010, vol 9, n 544), 4.

[10] Matthias Buck and Clare Hamilton, 'The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation to the Convention on Biological Diversity' (2011) 20 RECIEL 47, 54-56.

For this reason, and despite recognition of the importance of ILCs having a say in the utilisation of the natural resources located within their territories and their TK, this thesis acknowledges that ABS processes would be more efficient if each country in consensus with its ILCs designed a general and uniform process and MATs forms to obtain PIC and conduct benefit-sharing. This could be a more effective way to conduct ABS than seeking individual agreements with, possibly, different rules and processes (in accordance with given customary laws and protocols) each time there is an attempt to gain access to TK.

3.1.3 The Code of Ethical Conduct

The Tkarihwaié:ri Code of Ethical Conduct to Ensure Respect for the Cultural and Intellectual Heritage of Indigenous and Local Communities Relevant to the Conservation and Sustainable Use of Biological Diversity was adopted in the COP-10 of the CBD. It is important because it provides guidance to states concerning the development of local, national, or regional ethical conduct codes for the respect, preservation, and maintenance of TK.[11] This code is directed to those working with ILCs, specifically: 'government departments and agencies, academic institutions, private sector developers, potential stakeholders in development and/or research projects, extractive industries, forestry and any other actors eventually involved, and in particular for the development of activities/interactions on lands and waters traditionally occupied by indigenous and local communities while enabling the indigenous and local communities to promote respect of their traditional knowledge and associated biological and genetic resources' (Section 1. Rationale 3).

It contains some useful elements for the realisation of ABS processes, and incorporates many of the rights enshrined in the ILO Convention 169 on prior consultation. These elements are summarised as follows:

i. Recognition that the code should not be construed as altering or interpreting the obligations contained in the CBD and other international instruments, or be interpreted as altering domestic laws, treaties, agreements, or other constructive arrangements that may already exist.
ii. Understanding that TK is the intellectual property of ILCs and that concerns expressed by these communities about it should be acknowledged and addressed before the use of TK.

[11] CBD, Secretariat of the Convention on Biological Diversity, Tkarihwaié:ri. Code of Ethical Conduct to Ensure Respect for the Cultural and Intellectual Heritage of Indigenous and Local Communities Relevant to the Conservation and Sustainable Use of Biological Diversity, (Secretariat of the Convention on Biological Diversity, 2011).
'Section 1. Rationale: 1. The following elements of a code of ethical conduct are voluntary and are intended to provide guidance in activities/interactions with indigenous and local communities and for the development of local, national, or regional codes of ethical conduct, with the aim of promoting respect, preservation and maintenance of traditional knowledge, innovations and practices relevant for the conservation and sustainable use of biodiversity. (…)'

iii. Recognition of the collective property of ILCs over TK.
iv. The right of ILCs to receive fair and equitable benefits for the use of their TK.
v. Recognition of the integral connection of ILCs with the places they live.
vi. Understanding that access activities must not interfere with the traditional use of biodiversity on the part of ILCs.
vii. Regarding PIC, the code:
    a. Establishes that PIC is required for the development of activities taking place or impacting on sacred sites and lands and waters traditionally occupied by ILCs, or impacting upon a particular community.
    b. Contains the obligation to inform ILCs in advance about all the circumstances involving the interactions carried out that could affect them or their territories in a manner that considers their knowledge and cultural practices.
    c. Requires that PIC should not be coerced, forced or manipulated.
    d. Asserts that ILCs have the right to identify the authority who can grant PIC.
    e. Establishes the need for an inter-cultural dialogue with ILCs, avoiding the imposition of external concepts, standards and value judgments.
    f. Indicates that negotiations with ILCs must be conducted in good faith.

The existence of an international code of conduct emanating from the CBD should be helpful in providing guidance on the relationship between users and providers of TK. However, its voluntary nature is a cause for concern. Before the Code of Ethical Conduct of the CBD, there were other codes of conduct with similar objectives.[12] However, they seem not to have had the desired effect on the practices of biodiversity and TK users because, since their enactment, there have been many claims of unauthorised use of GR and TK.

Furthermore, although it is not possible to confirm that the unauthorised use of GR and TK is caused exclusively by the voluntary nature of these codes, experience shows that instruments backed up with enforcement powers are more likely to be implemented. In fact, the soft nature of the CBD is usually contrasted with the greater enforcement capacity of TRIPS in regard to the lack of compliance with the ABS rules within the processes for granting IPRs (this is explained in Chapter 6).

[12] For example the Code of Ethics of the International Society of Ethnobiology prime aim is 'serves to guide ethnobiologists and other researchers, business leaders, policy makers, governments, non-government organisations, academic institutions, funding agencies and others seeking meaningful partnerships with Indigenous peoples, traditional societies and local communities and thus to avoid the perpetuation of past injustices to these peoples.'
Also, this code's purpose is to 'reduce as much as possible the adverse effects of research (in all its forms, including applied research and development work) and related activities of ethnobiologists that can disrupt or disenfranchise Indigenous peoples, traditional societies and local communities from their customary and chosen lifestyles.'
International Society of Ethnobiology, 'International Society of Ethnobiology Code of Ethics (2006)' <http://www.ethnobiology.net/what-we-do/core-programs/ise-ethics-program/code-of-ethics/code-in-english/> accessed 15 August 2016.

The lack of enforcement capacity of the CBD may also explain why this Code of Ethical Conduct has been less disseminated than the NP, and why some of the commitments about the ILCs' rights over their TK in ABS processes are contained in a voluntary code instead of the Protocol. This was noted by Morgera, who described the Code of Ethical Conduct as 'the most discrete achievement of COP-10 in relation to indigenous and local communities.'[13] Moreover, without mentioning this code, Article 20 of the Protocol suggests that states should create this kind of instrument as voluntary guidelines for the development of the ABS process.

However, this thesis considers that the principles contained in this code should be implemented by the parties of the CBD through national laws rather than voluntary instruments. Without including these aspects in national laws, it would be more difficult for ILCs to benefit from the utilisation of their knowledge and to succeed in their reclamations on ABS infringements.

3.1.4 New concept of utilisation of GR

Paraphrasing the third objective of the CBD, Article 1 of the NP establishes as its main objective 'the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.'

It is important to note that the obligation to distribute benefits arises from the 'utilisation' of GR and associated TK. The concept of utilisation is therefore essential in understanding ABS. The next chapter discusses the implications of the concepts and elements in ABS. In this section, therefore, it will be noted only that, although the Protocol does not change the meaning of the term utilisation as described in Article 15.7 of the CBD, the NP does clarify the way in which 'utilisation of genetic resources' should be understood with respect to scientific research.

3.1.5 Simplified measures

Article 8a of the NP suggests the creation of 'simplified measures on access for non-commercial purposes, taking into account the need to address a change of intent for such research.' On the one hand, this provision expresses a concern from the scientific community regarding the alleged hindering of scientific research by the implementation of the Protocol. On the other hand, it also indicates providers' concerns about allowing simplified access to their resources for non-commercial research as this has the potential to change into commercial research.

[13] Elisa Morgera, 'Post-2010 Implementation' (2010) 40 Environmental Policy and Law 281, 285.

Both concerns are well founded. From the scientific community's perspective, it is true that ABS processes can demand a lot of time and money investment, which can cause delays. It is true, however, that some of the difficulties presented during the development of ABS processes are caused by the users' lack of planning of ABS activities, or even because conducting an ABS process for obtaining permission to utilise GR and TK was not considered as a step in the process of conducting the research.[14]

The classification of research into non-commercial and commercial may not be accurate as all research could potentially be non-commercial. The first step in all research processes is to conduct basic research to improve the understanding of the phenomena being studied or to build on the results of other studies. Usually, basic-research is assimilated to non-commercial research, for which it is often stated that basic-research should be free of ABS obligations, as explained in Section 1.2.2.c of Chapter 1. However, sometimes scientists may unexpectedly find commercial applications for their 'non-commercial' research or, in spite of the fact that the research was initially developed with the aim of having a commercial use, it is discovered during research that there is no viable commercial use.

From the provider's perspective, there is significant uncertainty about the ultimate destination and subsequent uses of their resources once they have been accessed. This way, some national ABS laws link the obligation to distribute benefits with the 'access' rather than the 'utilisation' of the resources (see Section 2.1.1 of Chapter 2). This manner of regulating ABS might be a response to the fact that, once access has occurred, providers have no power and cannot control the use of their resources. Such lack of control over accessed GR and TK includes the inability to find out about subsequent users and uses. Under the current conditions, it seems that the only way to know about other users and uses of accessed resources is through the information provided by the users. Given this situation, it is understandable that providers have a lack of incentive to facilitate access to their resources, even for laudable non-commercial scientific research initiatives.

3.1.6 From the disclosure of origin to an internationally recognised certificate of compliance

Discussions about the relationship between biodiversity and the Intellectual Property Rights (IPRs) are not new. However, during the negotiation of the NP, the debate was focused on the need to disclose the origin of GR and TK in IP applications, specifically in patent applications. The term 'disclosure of origin' means the action of revealing the country of origin and the ILCs from where the resources were taken. Regarding ABS, it is claimed that revealing the origin will help to fight the unauthorised use of GR and TK, which allegedly happens when

[14] Leidy Andrea Ávila Sánchez and others, 'Estudio Sobre las Solicitudes de Acceso a Recursos Genéticos' in Gabriel Ricardo Nemogá Soto and others, *La Investigación Sobre Biodiversidad en Colombia* (Instituto de Genética, Facultad de Derecho, Universidad Nacional de Colombia, 2010), 53-54.

a patent is granted to protect an invention based on a GR and/or TK that has been used without an ABS process being conducted.

This idea comes from the fact that ABS has not been incorporated into the process of granting patents, which means that IP offices may not be checking whether or not the resources utilised to develop the invention have been accessed and used according to the CBD. It is therefore highly probable that a large amount of GR and TK has been used for the development of inventions without the country of origin and/or the ILCs' authorisation. Furthermore, because IPRs confer ownership over intangible assets, it has been argued that GR and TK can be appropriated when such patents are granted. Although this is not true, technically speaking, the patent owner can prevent unauthorised persons from using the GR and/or TK in the same way as it is protected by its patent right. In reality, therefore, countries of origin and ILCs cannot use their resources in the same way as the patent owner, even when they have not authorised their utilisation, or the resources were utilised without following the ABS rules of the country of origin, or no benefits have been distributed.

This situation has resulted in claims that it is possible to misuse and misappropriate GR and TK through the IP system, and that an illegal patenting results from the lack of compliance with the CBD. In this context, during the negotiations of the NP, it was stated that such misuse, misappropriation, or illegal patenting could be avoided if patent applicants were obliged to declare the origin of the resources they use. Moreover, it was thought that an obligation of this type would help not only to verify whether GR and TK were used following the CBD, but also to corroborate whether the benefits derived from such utilisation were shared.

Notwithstanding the above, and despite the importance of the disclosure requirement to distribute benefits, countries did not reach an agreement on this issue during the negotiations of the NP. Furthermore, the references to the obligation to disclose the origin of GR and TK were deleted from the draft text of the NP. Instead, Article 17 introduced an 'internationally recognised certificate of compliance' to be produced by the provider country as proof of the legal access and utilisation of its resources. Needless to say, a certificate of compliance does not help providers to find the origin of the resources utilised by users, as it is only proof that certain resources have been used according to the ABS rules of a country. Thus, with an internationally recognised certificate of compliance, the origin of the resources accessed and utilised in patent applications remains unknown.

Disclosing the origin of resources is also necessary for distributing the benefits of shared GR and TK, where the same GR and TK are present in more than one country and/or ILCs. Biological and political borders are not necessarily the same, so different countries with similar environmental conditions can have the same biodiversity and, because of this, their ILCs in interaction with the same environment can develop the same TK.[15] With the exception of

[15] As is explained in more detail in the next chapter, TK is the result of an adaptive response of ILCs to the particular environmental conditions of the place they live.

endemic species, which are less frequent,[16] unless the user reveals the origin of the resources they have used, is very hard to know the identity of the provider of shared GR and TK. Similarly, the uncertainty about the country of origin could be used as an excuse not to distribute benefits. Concerning this issue, the NP suggest the creation of a global multilateral mechanism GMBSM (this is explained in Section 3.1.8 of this chapter), for which this thesis elaborates some recommendations in Chapter 7.

The differences between countries in this respect seem to suggest that this obligation will never be established by all countries. For example, within the World Intellectual Property Organisation (WIPO), the absence of an agreement on this matter resulted in the cessation of activities of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) for over a year. For around fifteen years, the IGC has been working on the protection of GR, TK, and traditional cultural expressions. Misappropriation is one of the issues dealt with by this Committee, so the disclosure requirement has also been negotiated in this forum. Its member states are almost the same as those of the CBD. Within the IGC, the countries have been discussing a draft text for preventing the misappropriation of GR and TK since February 2016.[17] In particular, Article 3 of the draft introduces the obligation to disclose the origin of the resources in IP applications. Seemingly, the majority of providers support mandatory disclosure of the origin of the resources in patent and other IP applications, while users claim that a mandatory disclosure requirement would introduce uncertainty into the patent system, risk patent invalidation in the case of non-disclosure, undermine the role of the patent system which seeks to promote innovation, and complicate the implementation of ABS.[18] Although the WIPO is a different forum from the CBD, negotiations within the IGC have opened a path in the search for a solution to this problem. The decisions taken by delegates will affect the application of the ABS rules of the CBD. Although no consensus has been reached so far, the discussions held within the IGC provide an idea about the positions and expectations of providers and users of GR and TK in this regard.

At present, the disclosure requirement has been established by some parties to the CBD.[19] However, the limited capacity of countries in the enforcement of their laws in other jurisdictions seems to suggest that unless a global solution is implemented, there is little

[16] See for example: Jay R Malcom and others, 'Global Warming and Extinctions of Endemic Species from Biodiversity Hotspots' (2006) 20 Conservation Biology 538, 544-547; John F Lamoreux and others, 'Global Tests of Biodiversity Concordance and the Importance of Endemism' (2006) 440 Nature 212, 213.

[17] WIPO, Secretariat of the World Intellectual Property Organisation, 'Consolidated Document Relating to Intellectual Property and Genetic Resources' (2015) WIPO/GRTKF/IC/29/4.

[18] ibid

[19] According to the information provided by the WIPO, as for October 2017 the countries establishing disclosure requirements are: the Andean Community of Nations, Belgium, Brazil, Burundi, China, Costa Rica, Cuba, Djibouti, Ecuador, Egypt, Ethiopia, the European Union, Germany, France, India, Indonesia, Italy, Kyrgyzstan, Namibia, Norway, Panama, Peru, Philippines, Romania, Samoa, South Africa, Spain, Sweden, Switzerland, Uganda, Vanuatu, and Viet Nam.
WIPO 'Disclosure Requirements Table' (October 2017) <http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf> accessed 09 May 2018

countries can do through their domestic laws to find out who is using their resources and how they have been used in other jurisdictions.

3.1.7 Compliance, check points and non-compliance

The NP does not regulate compliance. Instead, it suggests two ways in which it can be achieved: the observance of domestic legislation and the fulfilment of MATs. The first aspect is left to states to resolve through the development of legislative, administrative, or policy measures to provide that GR (Article 15.1) and TK (Article 16.1) utilised within their jurisdiction has been accessed in accordance with the domestic ABS legislation of the Party providing the resources. The second aspect is essentially limited to recommending the inclusion of procedural aspects in MATs, such as the jurisdiction, applicable laws, and options for alternative dispute resolution; and to indicate that each state shall ensure that ABS claims fall within their legal systems (Article 18). In summary, the provisions of the Protocol are limited to indicating that compliance is the responsibility of the parties involved in ABS processes, and that states are free to regulate on this matter.

It is important to note the shared responsibility between the provider and user states regarding observance of ABS. The responsibility of providers to set up the legislative, administrative, or policy measures for the development of ABS processes (Article 15.7, CBD) is complemented by the responsibility of users to ensure that GR and TK utilised within their territories have been accessed and utilised according to the provider's laws (Articles 15 and 16, Nagoya Protocol). Although the clarification made in the NP is quite obvious, it could be seen as a step forward in the achievement of compliance with ABS, because in the CBD the obligation of users in this regard are not clear.

The absence of sanctions in the CBD seems to indirectly encourage the lack of regulation on ABS. It may be affecting both setting up ABS processes and demonstrating that utilisation of GR and TK from foreign jurisdictions has been carried out according to the providers' regulations. The data provided in the previous chapter (out of 196 countries, only 57 have ABS measures) reveals that legal regulation of ABS has become a sort of optional decision of the Parties to the CBD. In addition, at an international level there is an absence of mechanisms dedicated specifically to achieving compliance with national developments based on the CBD and the NP, such as the WTO dispute settlement mechanism. This could result in major difficulties in achieving observance with local ABS laws.

Problems stemming from the absence of national or regional ABS laws have the potential to impact relationships between providers and users in different ways. For example, users of GR and TK in jurisdictions without an ABS law can perceive that what they are doing is legal because they have not broken any laws, even though they are accessing and using GR and TK without PIC, MAT, or distributing the benefits derived from such use to the providers. It is also possible that researchers as well as *ex-situ* collections in these jurisdictions have not integrated the ABS obligations into their practices and procedures. Providers could also face

more difficulty in achieving compliance with ABS in jurisdictions without an ABS law as, in the absence of such norms, there will be no tribunals or procedures to allow any legal actions to be brought. Under these conditions, it can be predicted that the enforcement of ABS commitments will be difficult for providers to achieve. Therefore, the national approach of the CBD to compliance with ABS appears to be an obstacle for achieving compliance when GR and TK are used in jurisdictions other than their country of origin. Based on the WTO's experience, an ABS mechanism with international reach could be expected to be more effective for achieving the distribution of benefits.

To support compliance, the NP suggests the designation of checkpoints. These are understood as any office that collects relevant information related to PIC, MAT, and/or to the utilisation of GR. Although there is no indicative list as to what these checkpoints might be, the Protocol does explain some of the functions they would fulfil (Article 17.1).[20] For Cabrera, despite the fact that no particular checkpoint is mentioned in the Protocol, IP offices best meet the characteristics.[21] In his opinion, the absence of a list of examples of checkpoints has resulted from the controversy that exists between the Parties to the CBD regarding the application of IPRs within ABS.[22] Regarding this, Jungcurt and others set out that, in order to prevent some countries from not signing the NP, it was agreed to not include any identified checkpoint in its text, so that their determination is the decision of each country.[23] Despite the difficulties experienced by the countries in this regard, it should be noted that there is nothing in the CBD or the Protocol to prevent the designation of national IP offices as checkpoints of compliance with ABS.

In addition, the fact that TK was not included in the monitoring activities described in the NP should not go unnoticed. This is because it can add difficulties for ILCs in finding out who is using their TK and, consequently, in achieving a distribution of benefits derived from it. Nonetheless, this could be explained because there is no direct reference to TK in the Article establishing ABS obligations in the CBD. Thus, creating checkpoints to determine TK utilisation is left in the hands of individual countries.

Finally, with regard to achieving compliance, the NP is limited to stating that countries shall take measures to address situations of non-compliance, and cooperate in cases of alleged violation of domestic ABS legislation (Articles 15.2, 15.3, 16.2 and 16.3).

Sensible aspects of ABS are not regulated by the NP. This seems to be the result of the lack of agreement of the countries on these matters. Perhaps this is why, in the Protocol, regulation of those aspects is left to the countries to solve through their national laws.

[20] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (adopted 29 October 2010, entered into force 12 October 2014) A-30619 UNTS (Nagoya Protocol), Article 17.

[21] Jorge Cabrera Medaglia, 'El Protocolo de Nagoya Sobre Acceso a Recursos Genéticos y la Propiedad Intelectual: Un paso adelante, muchos por recorrer' (2010) 11 Puentes 1, 3.

[22] ibid

[23] Jungcurt and others 'Summary of the Resumed Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 10-16 July 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 19 July 2010, vol 9, n 527), 9-11.

Although this is not a bad solution in itself, and is consistent with the CBD contents, the fact that the countries' different positions will be reflected in their national laws would make it more difficult to achieve benefit-sharing when access and utilisation happen in different countries. In this regard, it should be remembered that the Protocol was adopted more than fifteen years after the CBD came into force, in a climate of dissatisfaction caused by the limited distribution of benefits achieved. One of the issues that appeared to be clear at that time was that a national approach to compliance was leading to problems in the enforcement of ABS obligations in other jurisdictions. As will be explained in the following sections, the discussions held on this matter during the negotiations of the NP resulted in Articles 10 and 11 of its final text. Thus, the fact that the Protocol's text was produced in much the same way as the CBD seems to indicate that the decisions might be based more on political than legal or practical reasons.

The national approach of the CBD and its Protocol contrast sharply with the binding force provided at international level to the IPRs granted over creations using GR and TK.[24] The opposing interests of providers and users of these resources, as well as the under-capacity of providers to realise their interests in binding international agreements, can be observed in their texts. The official records of the negotiations of the NP demonstrate how user countries have constantly opposed any modification that could affect the granting of IPRs over inventions based on GR and TK, including the designation of IP offices as checkpoints to verify compliance with ABS.[25] This seems to be another matter of discussion about which it is not clear whether the countries could reach an agreement at some point in the future, or no agreement will be made.

3.1.8 Global multilateral benefit-sharing mechanism

As mentioned above, Article 10 of NP states that parties should consider a global multilateral benefit-sharing mechanism (GMBSM) for the distribution of benefits of GR and TK accessed in transboundary situations[26] and/or when PIC cannot be granted or obtained.

[24] The WTO's official web site that presents the importance or the dispute settlement system starts affirming that: 'The best international agreement is not worth very much if its obligations cannot be enforced when one of the signatories fails to comply with such obligations. An effective mechanism to settle disputes thus increases the practical value of the commitments the signatories undertake in an international agreement. The fact that the Members of the WTO established the current dispute settlement system during the Uruguay Round of Multilateral Trade Negotiations underscores the high importance they attach to compliance by all Members with their obligations under the WTO Agreement.'
WTO, 'Dispute Settlement System Training Module: Chapter 1 Introduction to the WTO Dispute Settlement System' <https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c1s1p1_e.htm> accessed 23 August 2016.

[25] Ibid (n 9)

[26] Regarding the cases which could be considered as 'transboundary situations', Eyal Benvenisti affirms that transboundary resources are those to which only a number of states have access. These resources can include fresh water, clean air, fisheries in shared rivers and lakes, hydrocarbon and mineral deposits, forests and rainforests, natural reserves and endangered species of flora and fauna. Thus, their main characteristic is their limited access to a number of states, whereby it is also possible to limit the access to other states.

This article resulted from the African Group proposal, which included the idea that ABS should support the conservation and sustainable use of biodiversity, and proposed that the benefits derived from the utilisation of:

i. GR located in common areas, understood as those over which countries cannot have or claim sovereign rights; and
ii. plant GR outside the MLS should be invested in the global preservation of biodiversity.

It seems that the intention was to invest the benefits produced by the utilisation of resources that do not belong to any country and those outside the scope of ABS, for the protection of global biodiversity, rather than to eliminate the possibility for countries to benefit from the use of their resources even in situations where these resources can be found *in-situ* in more than one country. The countries' willingness to receive compensation derived from the use of their shared resources appears to be clear during the negotiations of the NP.[27]

The original proposal consisting of investing the benefits in the global conservation of biodiversity was associated with the impossibility of claiming property rights over the accessed resources, rather than in the number of countries that potentially could claim property rights over such resources. It was clear that countries have the right to benefit from the utilisation of resources over which they can claim sovereign rights, even when the same resources can be found in more than one country. For this reason, it was proposed that the benefits arising from the use of resources in common areas be shared globally by investing them in the preservation of biodiversity in an abstract sense. However, in contrast to what it was proposed, Article 10 of the Protocol establishes that:

> 'Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge

On the contrary, to authors such as Zewdineh Beyene and Ian Wadley, transboundary resources are not only transected by a national frontier but also are capable of traversing that frontier 'by virtue of its state of flux.' Therefore, the main characteristic of transboundary resources is their capability to move, as occurs for example with water, rather than the fact of their limited access. It is important to notice that authors standing this position are more likely to be referring to transboundary waters management than to biodiversity management. In this way, from this classification are excluded static natural resources, such as biodiversity, and those that are capable of traversing a boundary because they are animals, for instance straddling and migratory species, including fishes or living natural resources which are passively transported by currents and tides.
By the above, the first concept of transboundary resources is adopted in this thesis.
Eyal Benvenisty, Sharing Transboundary Resources. International Law and Optimal Resource Use (CUP 2002), 2-3; Zewdineh Beyene and Ian L Wadley, 'Common Goods and the Common Good: Transboundary Natural Resources, Principled Cooperation, and the Nile Basin Initiative' (Breslauer Graduate Symposium on Natural Resource Issues in Africa at UC Berkeley, March 2004), 3-4.

[27] ibid (n 9)

associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.'

Article 10 of the Protocol is different from its original draft as it:

i. Changes the subject matter from GR over which it is not possible to claim sovereign rights (found in common areas) and those outside the scope of ABS to GR found in transboundary situations (i.e., those shared by neighbour countries at their borders);
ii. Includes TK in transboundary situations;
iii. Includes the situation in which PIC cannot be granted or obtained; and
iv. Changes the recipient of the benefits from the countries of origin and communities to a common fund created to invest the benefits in the global conservation and sustainable use of biodiversity.

These modifications significantly impact the distribution of benefits, mainly because countries will not directly benefit from the use of their resources. Perhaps because of this, in its 2016 meeting the Expert Group on Article 10 concluded that the need for such a mechanism remained unclear due to its narrow application and the insufficient information on and experience with ABS.[28] Nonetheless, this thesis considers that an ABS mechanism with global reach has a better chance of achieving benefit-sharing. For this reason, Chapter 7 includes some recommendations for the creation of a basic GMBSM on which the Parties could agree.

In order to understand the implications of Article 10 on ABS implementation, the following sections summarise its key points. They provide an explanation of the use of transboundary resources and access without PIC, together with an analysis of the investment of benefits in the global conservation of biodiversity.

A. Access in transboundary situations

Access in transboundary situations was addressed by the draft text of the Protocol in an article about transboundary cooperation. Accordingly, neighbouring parties should cooperate in implementing the Protocol where the same GR and/or TK are found *in-situ* within their territories:[29]

[28] CBD, COP-MOP, 'Report of the Expert Group Meeting on Article 10 of the Nagoya Protocol on Access and Benefit-Sharing' (2016) UNEP/CBD/NP/COP-MOP/2/10, 6.
[29] CBD, Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, 'Report of the First Part of the Ninth Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing' (2010) UNEP/CBD/WG-ABS/9/3, 47-48.

'Article 8. Transboundary Cooperation:

1. In instances where the same genetic resources are found *in-situ* within the territory of neighbouring Parties, those Parties shall cooperate, as appropriate, with a view to implementing this Protocol, in order to ensure that measures taken are supportive of and do not run counter to its objectives.

2. Where the same traditional knowledge associated with genetic resources is shared by different indigenous and local communities in several Parties, those Parties shall cooperate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

OR

1. Where the same genetic resources and/or traditional knowledge associated with genetic resources are found *in-situ* within the territory of more than one Party, those Parties shall cooperate with the involvement of the indigenous and local communities concerned, where applicable, with a view to implement the objective of this Protocol.'

Although it became Article 11 of the Protocol, its content changed considerably:

'Article 11. Transboundary Cooperation:

1. In instances where the same genetic resources are found *in-situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.'

In the Protocol, the word 'neighbouring' is deleted from the expression 'neighbouring Parties', leaving only the word 'Parties'. This small change fosters a shift in the understanding of the way in which ABS of shared resources should be addressed. First, the idea of neighbouring countries having the same resources *in-situ* refers to a situation in which the biological and political borders are not the same, so, as already explained in section 3.1.6 of this chapter, these neighbouring countries have the same biodiversity, i.e., they could share the same GR and TK. This is the situation, for example, between Ecuador, Peru and Brazil. In this sense, the draft Article 11 stated that neighbouring countries should cooperate to achieve the distribution of benefits of their shared resources. However, the existence of an Article about ABS in transboundary situations (where the resources could be found in more than one neighbouring country) together with the elimination of the word 'neighbouring' from Article 11 may indicate that it is referring to a situation in which the same resource could be found *in-situ* in more than one country which are not neighbours.

According to Articles 10 and 11 of the NP, therefore, the benefits derived from the use of a resource shared by neighbouring countries will not be received by the providers, but given

to a common fund, while the benefits from the use of resources shared by non-neighbouring countries will be distributed to the providers of the resources.

In theory, this new method of distributing benefits should not affect the interests of provider countries. However, it could be perceived as running contrary to the very nature of ABS for two reasons. On the one hand, at the international level, ABS discussions were motivated precisely by the wish of provider countries to participate in the benefits produced by the utilisation of their resources. Establishing the opposite of this therefore contradicts the original intention of the creation of ABS. On the other hand, the practical application of Article 10 could be affected. As stated in the CBD, the distribution of benefits encourages providers to facilitate access, which leads to utilisation. Without a direct distribution of benefits, therefore, there will be no reason for providers to allow facilitated access. In practical terms, this can be understood as an absence of motivation for providers to create a GMBSM to grant access to their resources, because under such a mechanism they will not receive a direct benefit. Without that mechanism, the benefits derived from the use of transboundary resources will be received by the country providing the resource, instead of being given to a fund for the global preservation of biodiversity. Given this, it is unlikely that states develop and/or implement the mechanism of Article 10 Nagoya.

Putting conditions on how providers benefit from the use of their GR and TK, for example, whether they can be accessed in a transboundary situation or not could also be interpreted as diminishing the sovereign rights of states over their GR and the rights of ILCs over their TK.

B. Access for which it is not possible to grant or obtain PIC

Access when PIC cannot be granted or obtained (access without PIC) is the second situation for which the creation of a GMBSM has been proposed. It may be thought that Article 10 puts together two different situations: access in transboundary situations and access without PIC, or not. One possible reason to put these aspects together in the same Article, is that users could face great difficulties in obtaining PIC for gaining access to transboundary resources. Such difficulties can arise when the Parties do not have ABS laws, or when GR and TK are stored in *ex-situ* collections, or databases without identification of the country of origin. In any of these situations, the user would not know who should grant PIC (given the importance of access *ex-situ* for ABS, this aspect is explained separately in the next section).

With regard to the resources in transboundary situations, or those that are shared by more than one country, or ILCs belonging or moving through different countries, this thesis maintains in Chapter 7 that the benefits should be equally distributed with all possible providers, because the impossibility of determining a single provider should not result in the benefits not being distributed.

Finally, it should be stressed that the establishment of a mechanism that allows access without PIC should only be considered for cases where it does not constitute a transgression

of countries' and ILCs' rights. Moreover, the impossibility to grant PIC should not be interpreted as a form of permission for the user to gain access to a resource when PIC has been expressly denied by the provider.

C. Access without PIC through *ex-situ* collections

Access without PIC is an issue that gains importance when the resource is accessed through an *ex-situ* conservation centre. For a very long time, natural resources have been collected and stored in *ex-situ* centres. However, the legal obligation to obtain PIC, conduct MATs and distribute the benefits was introduced in the CBD. This means that much of the biological material stored in *ex-situ* conservation centres was legally collected without PIC, MATs or a distribution of benefits before the CBD came into effect. As access and storage were possible without asking for permission (PIC), it is possible that in some cases the origin of the stored resources is unknown. It may also be possible that resources collected after the CBD came into force have been stored without conducting ABS processes and without any records about their origin. In other words, it is possible that not all resources whose origin is unknown were collected before the CBD. This clarification is important because ABS does not apply to GR collected before the CBD came into force, but only to those acquired subsequently. Under these conditions, it is not possible to obtain PIC, not only because it is not possible to know who the provider is, but also because the GR have already been stored in an *ex-situ* centre. The problem, in this case, is knowing who to distribute the benefits to, especially when there could be more than one possible provider, which could include neighbouring countries.

This situation casts further doubts on the way in which ABS should be conducted. As already mentioned in Section 3.1.8A above, Articles 10 and 11 of the Protocol offer different solutions for the distribution of benefits of shared resources depending on whether the providers are neighbouring countries or not. However, as the CBD did not regulate access *ex-situ*, it is not clear whether the distribution of benefits of shared resources stored in *ex-situ* collections without an identification of their country of origin (where it will not be possible to grant or obtain PIC) should be sought through the mechanism of Article 10.

Nevertheless, while it is true that the origin of some GR located in *ex-situ* conditions was not recorded, it is also true that the possible countries of origin can be determined. It would be closer to the nature of ABS (which seeks to ensure that providers can benefit from the use of their resources), if the benefits are distributed among all those possible providers instead of going to a global fund for the preservation of biodiversity. On this basis, a scale for the distribution of benefits through the common fund of Article 10 could be created, where all the possible provider countries would be the first to receive financial support.

D. The relationship between access without PIC, the *ex-situ* collections, and the Common Fund of the FAO ABS system

It could be claimed that investing the benefits derived from the utilisation of resources located *ex-situ* in the global preservation of biodiversity is coherent with the content of the Nairobi Final Act of the CBD. This Act requires that resources acquired before the CBD came into effect by *ex-situ* collections are addressed within the FAO Forum.[30] As explained in Chapter 5, under the Multilateral System MLS (ABS system) of FAO, benefits obtained from the utilisation of crops listed in Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) are sent to support conservation and further development of agriculture in the developing world. To that end, the resources are given to a trust fund. However, because the scope of this system is limited to plant GR listed in Annex I of the ITPGRFA, utilisation of GR outside this list should be carried out according to the CBD, meaning the benefits must be shared directly with the provider of the resource instead of being deposited in the FAO fund.

The scope of the MLS is determined by the crops listed in Annex I. Therefore, as long as a crop is included in the Annex, the benefits will be sent to the global fund. In order to understand the cases in which providers will have no right to benefit from the use of their resources, therefore, it is vital to have an understanding of the nature of the crops set out in Annex I. The annex comprises most of the crops needed for human nutrition. In other words, the crops are considered essential for world food security, for which no one can obtain IPRs. Thus, the similarity between the MLS and the GMBSM is that benefits derived from the use of plant GR listed in Annex I (i.e., the crops over which it is not possible to claim or obtain property rights) should be invested for global benefits. Furthermore, it could be affirmed that this is the same logic under used by the African Group regarding its proposal for the use of GR located in common areas, beyond national jurisdiction and collected before the CBD.

E. Utilisation of benefits for the conservation of biological diversity and the sustainable use of their components globally

The final aspect of Article 10 is the destination of the benefits collected through a GMBSM. As set out earlier, the initial proposal comprises resources beyond national jurisdiction, common areas and those collected before the CBD came into force. Article 8 of the Draft Protocol made it clear that provider countries were expecting to receive benefits from the utilisation of their resources, even in the case of shared resources. Nevertheless, negotiations concluded differently.

[30] José Esquinas Alcázar, Angela Hilmi and Isabel López Noriega, 'A Brief History of the Negotiations on the International Treaty on Plant Genetic Resources for Food and Agriculture' in Michael Halewood, Isabel López Noriega and Selim Louafi (eds), *Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance* (Earthscan from Rutledge 2013), 141-142.

As there was no mention of the benefits' ultimate destination, it could be inferred that providers would benefit from the use of their resources and would be able to freely decide how the money was invested. However, negotiations concluded with a text in which resources accessed in transboundary situations and those accessed without PIC fall under the treatment given to goods considered as part of the 'common heritage of mankind'.[31]

Goods belonging to the common heritage of humankind have two distinct characteristics. First, they are located in an international area whose characteristics[32] prevent ownership being assigned to all of humanity or to any sovereign user, i.e., ownership over the common area and the resources found there is legally absent (the Antarctic is an example).[33] The second characteristic is related to the mechanism used for the distribution of benefits. In principle, the area should be administered by the international community, and the benefits received from its utilisation managed through a common fund to ensure all humanity benefits from them.

As noted earlier, this method of distributing benefits matches perfectly with the content of Article 10 of the NP. However, there is a difference between the legal nature of the GR and TK described in this Article with goods located in common areas or beyond national jurisdiction, because particular entities, such as states and ILCs, can claim sovereign rights or exclusive property rights over them.

[31] As asserted by Antônio Cançado, at first, the concept of a 'common heritage of mankind' was used to define the legal status of resources in common space areas, such as the ocean floor, outer space, the moon and Antarctica. However, as explained by Kemal Baslar, its use has been extended by some authors and in some political pronouncements to include other areas, for instance, biodiversity preservation and living resources. Although the Preamble of the CBD declares that biodiversity preservation is a 'common concern' of humankind, rather than a 'common heritage', which is a very different legal concept, when incorporating a new way to conduct benefit-sharing, its Article 10 NP seems to treat resources in transboundary situations and TK, for which it is not possible to grant or obtain PIC, in a similar way to the way that resources are dealt with under the concept of a 'common heritage of mankind'. Nevertheless, it operates by way of exception to the ordinary rule contained in Article 15 CBD.
Antônio Augusto Cançado Trinidade, *International Law for Humankind. Towards a New Jus Gentium* (Second Edition, The Hague Academy of International Law 2013), 275-288; Kemal Baslar, The Concept of the Common Heritage of Mankind in International Law (Kluwer Law International 1998), 307-313.
[32] For Christopher Joyner, there are five elements that characterise this concept: (i) it applies to common areas that could not be owned legally in whole or in part by any State or group of States, legally the entire area would be administrated by the international community; (ii) all people would expected to share in the management of a common space area; (iii) if natural resources were exploited from a common space area, any economic benefits derived from those efforts would be shared internationally; (iv) use of the area must be limited exclusively to peaceful purposes; and (v) the conduct of research should be freely and openly permissible, so long as the environment of the common space area was in no way physically threatened or ecologically impaired, and the results would be made available as soon as possible to anyone who genuinely expressed interest in them.
Christopher C Joyner, 'Legal Implications of the Concept of the Common Heritage of Mankind' (1986) 35 International and Comparative Law Quarterly 190, 191-192.
[33] ibid, 194.

3.2 Non-agreed issues of the Draft Text of the Nagoya Protocol

The Nagoya Protocol has resulted from a long and arduous negotiation process. Since the beginning, ABS has been characterised as a polemic subject. Tensions between the interests of developing and developed countries (usually identified as provider and user countries) have demarcated its legal evolution. Such differences have determined the content of the final agreed texts of the CBD and the NP. For this reason, it is important to be aware of those non-agreed aspects of the negotiating text of the Protocol, as they provide a complete picture of the elements that a comprehensive ABS system should have. To that end, the following sections present each of those non-agreed matters.

3.2.1 Pathogens, viruses and their relationship with the WHO Pandemic Influenza Preparedness (PIP) Framework

The distribution of benefits derived from the utilisation of pathogens was initially opposed by the European Union (EU) during the 7th ABS meeting in Paris in 2009. The arguments against this have mainly been based on public interest and the negotiations held in other forums. On the one hand, it has been argued that the utilisation of pathogens should be excluded from the scope of the CBD because it is a fundamental issue related to human, animal, and plant health. On the other hand, it was suggested that human-health related concerns should be addressed by the WHO. Based on that, it was recommended that the distribution of benefits derived from the utilisation of pathogens and viruses should be addressed within negotiations under the Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits.[34] For their part, developing countries considered that such a proposal would harm their interests. They believed that the real intention behind that proposal was to avoid the sharing of benefits derived from the utilisation of GR in a highly profitable sector.[35]

3.2.2 GR for food agriculture

ABS is an obligation triggered by the utilisation of GR and TK. The CBD does not envision differential treatment based on the type of usage, such as scientific research on medicine, agriculture, or cosmetics. It could, therefore, be argued that ABS should be conducted when GR and TK are used in any way. That is why, for example, the NP only suggests the creation of simplified measures for the non-commercial use of these resources. In theory, GR for agriculture falls within the scope of the CBD. However, it must be considered that agricultural issues are usually implemented under the FAO Forum. As explained in Chapter 5, the FAO has

[34] CBD, Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, 'Report of the Seventh Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing' (2009) UNEP/CBD/WG-ABS/7/8, 11.
[35] Jungcurt and others (n 23) 15.

its own ABS system for the distribution of benefits derived from the utilisation of plant GR for food and agriculture with regard to the crops listed in Annex I of the ITPGRFA. These resources are outside the scope of the CBD and within the scope of the FAO.

On this basis, it has been argued that difficulties in ABS implementation are also caused by the fact that the distribution of benefits derived from GR and TK utilisation is regulated by more than one international treaty. On this subject, different opinions can be found. For example, authors such as Rosendal and Steinar consider that the interaction, overlap and complexity in the ABS regime can be understood as an externality to the negotiation of ABS, and as a strategic move by negotiating parties.[36] For their part, Esquinas Alcázar, Hilmi and López Noriega affirm that the CBD does not take into account the specific needs of the agricultural sector because it was weakly represented during its negotiations.[37] Chapter 6 deals with this issue in more detail. Among other things, it concludes that complexity and fragmentation are the cause of the inefficiency and/or failure to adequately implement international laws and that this could be one of the causes for the limited application of ABS.

3.2.3 *Ex-situ* conservation centres

As presented in Section 1.2.2.c of Chapter 1, access to GR *ex-situ* has been a matter of great controversy. Nevertheless, it seems clear that the link between the CBD and the FAO forums was established in May 1992 during the final meeting of the CBD in Nairobi. A group of negotiators managed to draft a resolution on agricultural biodiversity to be incorporated in the Nairobi Final Act of the CBD. It became Resolution 3 of the Nairobi Final Act and recognised that certain matters were left out of the Convention, including access to GR collected and stored in *ex-situ* conservation centres before the CBD came into effect, and the realisation of farmers' rights.[38]

For this reason, it was requested that these matters be addressed within the FAO Forum.[39] Resolution 3 of the Nairobi Final Act appears to suggest that, for those cases where the resources have been accessed through *ex-situ* collections, and whose materials were not collected in accordance with the CBD (because it had not yet entered into force), the ABS rules of the FAO should apply. However, taking into account the historical moment of the Nairobi Final Act, it seems to be clear that the intention of the negotiating parties was to create a

[36] Kristin Rosendal and Andresen Steinar, 'Complexity of International Institutions: Implications for Access and Benefit Sharing' (2015) 11 Trade Insight 28, 29.

[37] Esquinas Alcázar, Hilmi and López Noriega (n 28) 141.

[38] Nairobi Final Act of the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity (1992) 31 ILM 842. Resolution 3: The Interrelationship between the Convention on Biological Diversity and the Promotion of Sustainable Agriculture. The Conference,

'4. Further recognizes the need to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular: (a) Access to *ex-situ* collections not acquired in accordance with this Convention; and (b) The question of farmers' rights.'

[39] Esquinas Alcázar, Hilmi and López Noriega (n 28) 141-142.

solution for the management of the biological material collected before the existence of the CBD, rather than to concede free access to GR *ex-situ* or to exclude it from ABS.

3.2.4 Publicly-available TK

Publicly-available TK refers to the knowledge that has been made accessible to the public. As explained in Section 1.2.2.e of Chapter 1, very often this situation is understood as referring to TK in the public domain. In fact, at the Expert Group Meeting on Article 10 of the Nagoya Protocol in 2016, it was considered that access to publicly-available TK is one of the situations in which it is not possible to grant or obtain PIC.[40] It could, therefore, be interpreted that the GMBSM of Article 10 NP is making reference to TK in the public domain. Nonetheless, available TK and TK in the public domain are two completely different things.

Much TK has been released to the public as a consequence of the practice of some social sciences professionals of entering ILCs' territories to record, photograph, document, reproduce, and communicate to the public their traditional lifestyles, including TK.[41] This situation could have two particular consequences. First, the ILCs may lose control over their TK. Secondly, in most cases, public communication of ILCs' lifestyles has been without the consent of communities, or even without their knowledge. This thesis considers that it is not possible to ascertain the extent to which TK has been disclosed into the public domain without the consent or knowledge of ILCs.

The public domain is a concept related to the exercise of intellectual IPRs. An asset belongs to the public domain when IPRs over it cannot be exercised, mainly because of the expiration of the term of protection. The immediate consequence of this is that goods in the public domain are available for anyone to use without limitation. Given this, the notion of public domain involves the prior existence of a right. This is important because, nowadays, the IPRs of ILCs over their TK have not yet been recognised through an international instrument. It is not, thus, accurate to claim that a right has ended when it has never existed. Moreover, under the IP rules, the holder of an IPR has the power to control the public communication of the IPR-protected good. In other words, before the time of protection has expired, it is only possible to make an IPR-protected good available to the public through the authorisation of the rightful holder. In applying these rules to TK, considering disclosed TK to be in the public domain seems contrary to the IP logic.

Finally, publicly-available TK was not included in the NP for two main reasons. First, at the March 2010 sixth meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-sharing, the EU opposed any reference to such knowledge in the Protocol arguing that this issue was being discussed in the IGC of WIPO.[42] In other words, the EU considered that TK protection is an issue which belongs to the IP field. However, as explained in Chapter 6, one of

[40] COP-MOP (n 28) 5.
[41] ibid (n 8).
[42] CBD (n 29) 18.

the effects of fragmenting the same topic into different issues to be addressed in various forums could be the non-recognition of some of the rights of other negotiating parties.[43] Second, it was considered that sharing the benefits arising from the utilisation of available TK is difficult to achieve because a mechanism of this kind should operate without subjecting the knowledge to requirements of IP protection, while at the same time ensuring a distribution of benefits with TK right holders.[44]

3.2.5 GR over which it is not possible to claim or obtain property rights

During the negotiations of the Protocol it was suggested that the following be included: (i) GR in the Antarctic Treaty Area and (ii) marine GR from areas beyond national jurisdictions within the scope of ABS. Provider countries proposed adding the continued and new uses of lawfully-acquired GR before the CBD, and the African Group suggested that plant GR outside the MLS be included. The establishment of a trust fund to be used for conservation and sustainable use of global biodiversity was recommended to distribute benefits derived from the utilisation of such resources.[45]

These initiatives were made within the discussions on the temporal and geographical scope of the NP, which included a review of the content of Article 7 of the Revised Draft:[46]

> 'Article 7. Contribution to Conservation and Sustainable Use:
> Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation and sustainable use of biological diversity in support of the objectives of the Convention.'

This Article suggested that those directly benefiting from the use of GR should invest these benefits in the conservation and sustainable use of biodiversity, in line with the objectives of the CBD.

However, and in spite of the fact that these proposals are at the root of the GMBSM of Article 10, proposing that the benefits derived from the use of resources in common areas and areas beyond national jurisdictions are invested for the general benefit is different from proposing that providers of resources in transboundary areas will not benefit from their utilisation. Areas without national jurisdiction are not the same as boundary areas between countries, and the absence of sovereign rights over a particular area is not the same as finding the same resource *in-situ* in more than one country. In the first case, countries cannot claim sovereign rights over the resources found there, whereas in the second case they can.

[43] Rosendal and Steinar (n 36) 29.
[44] Jungcurt and others (n 23) 15.
[45] ibid 5.
[46] CBD (n 29) 47.
Annex I. Revised Draft Protocol on Access to Genetic Resources and the Fair And Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.

The distribution of benefits in the GMBSM would be more logical if Article 10 had been maintained in its original version. It is reasonable to invest the benefits produced by the use of resources that cannot belong to any country in the global preservation of biodiversity.

3.3 Utilisation without access (the use of databases of genetic sequence data and new technologies such as synthetic biology and bioinformatics) – a non-discussed issue

Discussions over this matter could not be found in the reports of the negotiation meetings for the agreement on the NP.[47] However, this issue is important because current technologies allow researchers to conduct scientific research on GR using the information contained in databases of genetic sequence data without the need to use the GR material. In other words, it is possible to utilise a GR without physically accessing it.

Because access without utilisation is not included in ABS, but allegedly some technologies allow it (such as synthetic biology and bioinformatics), its inclusion within the scope of ABS is currently under consideration by the Parties to the CBD.[48] Also, it is a topic debated by some scholars which has led to the creation of the term 'digital biopiracy', as explained in Section 1.2.2.d of Chapter 1.

4. Conclusions

The CBD acknowledges the right of states to concede access to, and benefit from, the utilisation of GR and associated TK, based on the recognition of their sovereign rights over natural resources within their frontiers. Despite the enormous achievement the creation of an international agreement on ABS represents, the lack of agreement on sensitive issues affected its design and have resulted in a reduced distribution of benefits.

Regarding its enforceability, the first element to note is that the CBD operates as an aspirational policy-oriented agreement in which provisions are commonly expressed as general goals and policies rather than as concrete obligations. Because of this, it does not have enforcement mechanisms to impose sanctions on Parties which do not comply with its rules. Consequently, ABS compliance is in the hands of the parties through the development of national laws, and thus, dependent on the enforcement capacity of states, which is limited to their territories.

The Nagoya Protocol reproduces the contents of the CBD and does not modify its obligations. As a result, like the CBD, it is limited to suggesting that compliance with ABS should

[47] Johannes Gnann and others, 'Summary of the Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 22-28 March 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 31 March 2010, vol 9, n 503); Jungcurt and others (n 26); CBD (n 29).

[48] Jerome H Reichman, Paul F Uhlir and Tom Dedeurwaerdere, *Governing Digitally Integrated Genetic Resources, Data, and Literature. Global Intellectual Property Strategies for a Redesigned Microbial Research Commons* (CUP 2016), 148.

be achieved by each state through the strengthening of domestic legislation and contractual obligations (MATs).

Implementing the GMBSM proposed in Article 10 of the Protocol requires that the countries enter in new negotiations. For this reason, it is unclear whether the countries will negotiate and, if so, whether they could reach agreement on the way the GMBSM should operate. Chapter 7 contain few suggestions regarding the minimum elements needed for such a mechanism to operate and, on which, the countries can come to agreements.

Another reason for the lack of efficiency of ABS is that many important aspects have been left out, particularly regulation of: (i) access *ex-situ*; (ii) resources in the public domain; (iii) the continued and new utilisations of resources accessed before the CBD; and (iv) utilisation without access.

CHAPTER 4. Content and scope of the ABS system of the CBD and the NP

1. Introduction

The previous chapter concluded that the design of ABS could be considered as an element affecting the distribution of benefits. This is primarily due to its national/bilateral approach and because access *ex-situ* and the public domain were left out of its regulation.

This chapter continues examining the content and scope of the elements of ABS to determine whether the content also could be a factor affecting the limited distribution of benefits, as evidenced in Chapter 1 in the number of MATs reported to the ABSCH.

To this end, the chapter has been divided into five sections. The first examines the core concepts of ABS, the second its scope, the third its structural elements, the fourth its obligations, and the final section examines the parties involved in an ABS transaction. Each section starts with an explanation of the content of the CBD, followed by the clarifications made by the NP.

The chapter concludes that ABS does not do justice to reality. For example, it only regulates access *in-situ*, it does not include the public domain, and its content does not take into consideration the way scientific research is carried out in practice and therefore the concepts of GR and utilisation, and the way in which GR and TK are accessed, do not correspond to the way in which scientists actually work. Consequently, the content of ABS appears to be another element undermining the distribution of benefits.

2. The core concept of ABS

There are countless definitions of ABS.[1] All of them agree on the basic idea contained in the CBD and the NP: users of GR and TK have the obligation to distribute the benefits to the provider arising out of utilisation of the resources in a fair and equitable way.

As briefly mentioned in Chapter 3, this obligation was included in the CBD with the objective of supporting the conservation and sustainable use of biodiversity. For this purpose, the distribution of benefits was established as a means of supplying monetary and non-monetary aids to providers of GR and TK, who would invest those resources in the preservation of their biodiversity *in-situ*. This notion is integrated into the Preamble of the CBD, which states that 'the provision of new and additional financial resources and appropriate access to relevant technologies can be expected to make a substantial difference in the world's ability to address the loss of biological diversity' for which 'substantial investments are required' and such an investment is justified by the fact that it is expected to produce 'a broad range of environmental, economic and social benefits.'

[1] For example it has been defined as 'the action of giving a portion of advantages/profits derived from the use of genetic resources or traditional knowledge to resource providers.'
Doris Schroeder, 'Benefit Sharing: It's Time for a Definition' (2007) 33 Journal of Medical Ethics 205, 206.

Despite the advantages that ABS is supposed to bring for the environment, the economy, and society, the Parties to the CBD do not seem to be sufficiently motivated to develop and/or implement its measures, as seen in Figure 1 of Chapter 2. Apart from the limitations derived from the way in which the system has been designed, it is possible that the implementation of ABS has also been hampered in part by failures in the content, scope, and conceptual and legal definition of the elements comprising the distribution of benefits. To be certain as to whether or not this is the case, details of the scope and elements of ABS are set out below.

3. The scope of ABS

The scope of ABS is contained in Articles 1 and 3 of the CBD and the NP, respectively. As mentioned throughout this thesis, these Articles create an obligation to share the benefits produced by the use of GR and associated TK. The scope of ABS is therefore determined by the ambit and content of the words 'utilisation', 'genetic resource', 'traditional knowledge', and 'fair and equitable distribution of benefits'. In this respect, the discussion does not relate to whether there is an obligation to share benefits (which appears to be clear), but rather on the definition of the situations in which an ABS obligation exists.

Discussion about the length and scope of the elements triggering the obligation to distribute benefits continues to this day. Questions such as what a GR is, how to identify when a resource has been used as a genetic or a biological material, and whether the way in which it has been used (for example through the application of biotechnological tools) can serve to determine whether a sample was used as a genetic or a biological material remain unanswered.[2] A similar situation surrounds the issue of how to integrate ABS with the rights of ILCs when TK has been used.

Given this, this section studies the content of the elements comprising the scope of ABS. Such analysis will provide important insights into the current obstacles that countries might face when producing and implementing ABS measures.

3.1 Utilisation

There is an obligation to distribute benefits when GR and TK are 'used'. Because of this, knowing the precise scope of the term 'utilisation' is vital in determining when an ABS obligation exists. Despite this, the CBD does not define 'utilisation' as it does other terms, such as biotechnology and GR.

Nevertheless, while the concept of utilisation cannot be found in the Article of 'definitions' in the CBD, its meaning can be extracted from the content of Article 15.7, which states that there is an obligation to share in a fair and equitable way 'the results of research

[2] Thomas Greiber and others 'An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing' (IUCN Environmental Policy and Law Paper No. 83) (2012), 85.

and development and the benefits arising from the commercial and other utilisation' of the resources accessed. It is therefore possible to argue that for ABS purposes, utilisation means conducting research, development and commercialisation activities, and other kinds of utilisation of GR and associated TK. For ten Kate and Laird, the use of the expression 'other utilisation' opens the door to considering activities other than research or commercialisation, such as horticulture, crop protection, or health care as 'utilisation'.[3] Moreover, as technology is in constant evolution, the expression 'other utilisation' might be intended to cover the application of technologies not yet developed, but that in the future will definitively involve the utilisation of GR and TK.

Finally, it should be mentioned that the idea of benefitting from 'other utilisations' of the resources has its origin in the negotiations of the CBD. At that moment it was said that the distribution of benefits 'can only be effective if it extends to products and processes developed along the value chain.'[4] In this way, it was expected that the concept of utilisation in the CBD also covers a broad range of activities carried out when GR and TK are used, as well as their subsequent applications in the market.

For its part, Article 2c of the Nagoya Protocol defines utilisation of GR in the following terms:

> '(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;'

The Protocol's definition mentions the application of biotechnology in such activities. Although it may seem obvious that the use of GR in any kind of scientific research falls within the scope of ABS, the reasons for including this clarification in the NP can be appreciated in the records of its negotiation. At that time, a number of developed countries, led by the USA and Japan, opposed the distribution of benefits arising from the use of GR and TK forming the basis of products obtained following the application of biotechnology.[5] The countries also discussed the possibility of including 'derivatives' in the scope of ABS. These positions made negotiations difficult. Tsioumani explains that in order to reach agreement, the countries accepted the compromise package proposed by the Japanese COP Presidency. This included, in the Protocol, the definitions of 'utilisation of genetic resources', 'biotechnology', and 'derivatives' in relation

[3] Kerry ten Kate and Sarah Laird, *The Commercial Use of Biodiversity. Access to Genetic Resources and Benefit-Sharing* (Earthscan Publications Ltd 2000), 1-3.

[4] Greiber and others (n 2) 85.

[5] In this regard, it is precise to remember the position of the USA and Japan in the WTO by the time of discussions about the relation between trade and nature. These countries claim to have property rights over the natural resources modified using biotechnology, and at the same time they refused to accept the obligations of PIC and MAT of the CBD.
Amy Dwyer, 'Trade-Related Aspects on Intellectual Property Rights' in Terence P Stewart (ed), *The GATT Uruguay Round a Negotiating History* (1986-1994) (Kluwer Law International 1999), 473.

to biotechnology, but did not include 'derivatives' within the scope of ABS and did not use this term in the rest of the Protocol's text.[6] Jungcurt and others affirm that this solution allows each country to decide whether to include derivatives in their ABS law, without creating this as a general obligation for all the Parties to the NP.[7] (The implications of the inclusion of this term within the scope of ABS is explained in Section 3.2.3 of this chapter.)

The question here is why the countries opposing the inclusion of derivatives within the scope of ABS allowed for the possibility of other countries including them in their national ABS laws, when there is the obligation for users to comply with the rules of provider countries. In other words, why did they allow this at national level but not international level when GR and TK have to be accessed according to the provider's country law? Whatever their motivations, this appears to indicate that countries may be aware of the difficulties in achieving international compliance through the implementation of national or regional laws. Seemingly, the countries are willing to accept commitments regarding ABS to the extent that they are not included in international instruments, but in national laws.

Finally, regarding TK, although it is true that TK is not mentioned in the concept of utilisation, it is reasonable to conclude that providers of TK are entitled to compensation every time their knowledge is used in association with a GR which has been utilised.

3.1.1 Examples of utilisation in the CBD and the NP

The notion of utilisation has two distinct elements: first the kind of resources that can be utilised in ABS contexts; and second the ways in which such resources can be used.

According to the NP, ABS processes have to be conducted for the utilisation of GR, its biochemical composition, and associated TK. This mean that there is no obligation to share the benefits derived from the use of other resources, such as biological resources, human genetic resources,[8] or TK not associated with GR or traditional cultural expression.

In terms of the kind of activities that could be considered as 'utilisation', based on the contents of the CBD and the NP, it can be affirmed that utilisation is:

i. Conducting research and development, including the use of different technologies, such as biotechnology;
ii. The commercialisation of the products developed from the research and development activities;

[6] Elsa Tsioumani, 'Access and Benefit Sharing -The Nagoya Protocol-' (2010) 40 Environmental Policy and Law 288, 289.

[7] Stefan Jungcurt and others, 'Summary of the Resumed Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 10-16 July 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 19 July 2010, vol 9, n 527), 6.

[8] The decision of excluding human genetic resources from the ABS framework is contained in paragraph 2 of the Decision II/2 of the Conference of the Parties to the CBD.
CBD, Conference of the Parties (COP), 'Access to Genetic Resources' (1995) UNEP/CBD/COP/2/19, 22.

iii. The commercialisation of the resources regardless of whether they have resulted from the abovementioned activities or not;
iv. The subsequent applications of the use of such resources; and
v. Any other kind of utilisation, which could include, for example, horticulture, crop protection or health care, and the future use of technologies that have not yet been developed.

Table 7. Examples of 'Utilisation' of GR and TK

Collection and identification.
Conservation: maintenance of stocks for research through deposition in diverse collections, breeding centre, etc.
Characterisation and evaluation. E.g. sequencing genes or genomes, phenotyping of the characteristics of plants, animals and micro-organisms, experimental evaluation of heritable characteristics, creation of collections of reference specimens in repositories, and isolation of a compound from genetic material for the purpose of characterisation and evaluation.
Genetic modification. E.g. transfer of a genetic trait, such as gene for pesticide resistance taken out of one species and put into another; genetic modification of a micro-organism for a specific purpose such as the production of enzymes or biofuels; production of recombinant cell lines or attenuated vaccine strains; production of transgenic organisms, animals, plants, microorganisms; use of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA), and direct injection of nucleic acid into cells or organelles; and se of fusion of cells beyond the taxonomic family.
Biosynthesis: use of GR as a 'factory' to produce organic compounds, such as, antibodies, vitamins, hormones, enzymes, active compounds for pharmaceutical production, and other naturally occurring compounds.
Production of naturally occurring compounds. E.g. screening and extraction of metabolites from genetic material, chemical synthesis of metabolites occurring in genetic material, synthesis of short DNA segments based on genetic material (e.g. oligonucleotides, probes and primers), and production of copies of DNA segments through PCR (polymerase chain reaction amplification).
Breeding and selection, including domestication.
Propagation and cultivation of the GR in the form received, including: cultivation of microorganisms or plants; propagation of animals; and production of plant, animal and microbial products.
DNA synthesis.
Distribution of GR and TK.

This table has been made by the author based on the information contained in the document produced by the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing of the CBD 'Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches' (2008) UNEP/CBD/WG-ABS/7/2, 7-8, 12-13

Accordingly, a list of examples of cases when GR and TK have been used is provided in Table 7. The Table shows that the ABS obligations can potentially apply to a broad range of

research and development activities as well as their subsequent commercial applications in different fields (including plant breeding, cosmetics, medicine and the pharmaceutical industry). However, this is not an exhaustive list of the types of utilisation of these resources.

In the opinion of Buck and Hamilton, the fact that a difference between 'utilisation' and 'subsequent applications and commercialisation' of the resources is emphasised might imply that the activities following the use of GR and TK will need to be carried out on the basis of the content of what has been agreed on MATs. For them, this situation presupposes that, in turn, the parties to an ABS transaction should make a proper decision upon access, i.e., they should know or at least anticipate the potential future use of the resources so they can agree on their possible subsequent applications and commercialisation.[9] However, in spite of the importance of appropriate planning for successful ABS negotiation, in practice, the impossibility of anticipating all the future consequences derived from the utilisation of GR and TK is one of the reasons that monitoring and control is so difficult. Perhaps because of that, the possibility of a change in the intended use of the resources from non-commercial to commercial has been contemplated as a probability in ABS transactions. However, monitoring and controlling the further utilisation of GR and TK (which increases the possibilities of benefitting from the use of these resources) would be better addressed if an ABS mechanism with some level of international reach was implemented, such as a GMBSM.

It follows that although there is no definition of the term 'utilisation' in the CBD, and that this is mainly linked to research activities in the NP, the CBD contains enough elements for countries to establish a broad range of activities as 'utilisation of GR and TK' within their national ABS laws.

3.1.2 Use of GR by *ex-situ* conservation centres

Ex-situ conservation centres were initially created for storing and preserving samples of biodiversity. Because of this, there is debate as to whether or not the storing activities performed by these centres constitute 'utilisation' of GR and, consequently, if they have to comply with ABS obligations. In spite of their original intention, it cannot be denied that today, the vast majority of these centres have ceased to be merely storage facilities and perhaps have become the biggest providers of GR and their related information according to the figures published by the FAO regarding the number of samples accessed through the MLS.[10] In addition, this is allegedly happening without following the ABS rules.[11] Moreover, even in the

[9] Matthias Buck and Clare Hamilton, 'The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation to the Convention on Biological Diversity' (2011) 20 RECIEL 47, 52.

[10] CBD, COP-MOP, 'Update on recent developments under the International Treaty on Plant Genetic Resources for Food and Agriculture of relevance to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation' (2016) UNEP/CBD/NP/COP-MOP/2/INF/10.

[11] As noted by Myrna Watanabe, disclosing the scientific data obtained from the accessed resource is the benefit usually received by the *ex-situ* collections providing GR. This clearly leaves out the participation of providing countries in regards to the decision of granting access and the negotiation of the benefits to distribute.

case where *ex-situ* centres are solely storing biological materials, the Expert Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches of the CBD considers the activities of collection and conservation as types of use of GR (see Table 7 above).

Moreover, Article 13.1 of the ITPGRFA, establishing the MLS, acknowledges that accessing the resources 'constitutes itself a major benefit' of the ABS system. Following this logic, even in the case where an *ex-situ* centre only acts as a storage facility, the resources it preserves should be acquired under the CBD rules. It also should be remembered that *ex-situ* centres have to gain authorisation of the country of origin when acting as providers of GT.

Nevertheless, it seems that the absence of regulation for *ex-situ* conservation centres in the CBD poses many constraints and difficulties for ABS. This is why it can be affirmed, that their regulation is crucial for a better implementation of ABS.

3.2 Genetic Resources (GR)

The subject matter of ABS (GR and TK) is another crucial element that serves the purpose of determining when the obligation to distribute benefits arises. An analysis of this element starts in this section with the examination of the concept of GR, preceded by a short discussion of the concept of biological diversity. It should be noted that this analysis does not include considerations of GR and TK as information. This is not due to a lack of consistency in such a proposal, but because this section is intended to analyse the contents of the CBD and the NP. The discussion of GR and TK as information can be found in Chapter 7, where the proposals for the improvement of ABS are analysed.

Although the ABS scope does not include biological resources, the distinction made in the CBD between biological resources and GR might be difficult to identify in practice, because they are contained in biological resources. This means, that, when someone gains access to a GR, in practice, he/she is sometimes accessing a biological resource. Thus, the determination of the type of the resource that has been accessed (biological resource or GR) will depend on its use, with respect to what is understood as the 'functional units of heredity' (this will be explained later in this section). Hence, it is important to know the difference between these concepts.

According to the CBD, biological resources 'includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.' That is, GR form just one part of many elements comprising biological resources. Consequently, it is understandable that accessing and using biological resources does not necessarily imply that a GR has been used and, therefore, that a benefit-sharing obligation has emerged.

GR are defined in the CBD as 'any material containing functional units of heredity.'

Myrna Watanabe, 'The Nagoya Protocol on Access and Benefit Sharing. International Treaty Poses Challenges for Biological Collections' (2015) 65 BioScience 543, 548.

Notably 'functional units of heredity' serves to determine what a GR is, and that is why it is important to understand what this concept means. Tvedt and Young observe that this term is not defined anywhere in the CBD, and was selected by policymakers rather than genetic scientists, so that it was never clarified.[12] From a technical definition, Glowka, Burhenne-Guilmin, and Synge understand that 'functional units of heredity' incorporates DNA and RNA.[13] However, in their opinion, finding a definition of this concept 'is made more difficult by the fact that the CBD does not use the term gene or DNA-molecule or any other more definite term, possibly in an effort to maximize the flexibility of Article 15 and enable it to cover the evolving state-of-the-art in the utilization of genetic material.'[14] As observed in Chapter 2, this lack of clarity has generated the inclusion of different elements within the ABS scope in national laws (see Table 1). Nevertheless, the mention of 'functional units of heredity' as the differentiating element in this concept seems to suggest that a good starting point for the establishment of ABS obligations could be the use of biological materials containing these units.

To the concept of the CBD, Article 2c of NP adds the 'biochemical composition of genetic resources' and defines 'derivatives' in connection with the biotechnological use of GR.[15] However, the Protocol does not provide a concept for 'biochemical composition' nor does it mention 'derivatives' in any other section of its text. This legal vacuum has been filled by the Parties to the NP through their national laws, and may result in three consequences: (i) variation between national laws and a flexible understanding of this notion;[16] (ii) an increase in the transactional costs of the ABS processes due to fragmentation and complexity; and (iii) difficulties in tracking and monitoring the use of the resources, since not all countries will report the same activities because 'access' and 'utilisation' can be interpreted by each Party and, therefore, these concepts could be different from one country to another.

Doubts about the possible negative effects of the concept of GR on ABS transactions

[12] Morten Walløe Tvedt and Tomme Young, 'Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD' (IUCN - The World Conservation Union, Environmental Policy and Law Paper No. 67/2, Fridtjof Nansen Institute, ABS Series No. 2, 2007) p. 54

[13] Lyle Glowka, Françoise Burhenne-Guilmin, and Hugh Synge, *A Guide to the Convention on Biological Diversity* (IUCN - The World Conservation Union, Environmental Policy and Law Paper No. 30, 1994) p. 21-22 ; (n 12) p. 54

[14] (n 12) pp. 54-55

[15] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (adopted 29 October 2010, entered into force 12 October 2014) A-30619 UNTS (Nagoya Protocol).

'Article 2. Use of Terms:

d. "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

e. "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.'

[16] For example, interpreting Article 2 of the Nagoya Protocol Costa Rica has determined that access is the 'action to obtain samples of components of biodiversity, wild or domesticated, in *in-situ* or *ex-situ* conditions, or to obtain associated knowledge, with basic aims of research, bioprospecting or commercial use'. (Costa Rica, Biodiversity Law No. 7788, May 27 1998, Art 7). Accordingly, it could be understood that users must have to conduct an ABS process to access any component of the Costa Rican biodiversity. This means that Costa Rica is required to make an enormous inversion in economic and human capital to reinforce its institutional structure and to respond to all these access applications adequately.

are frequently expressed (see, for example, Rosell and Chaparro in Section 3.2.2). Furthermore, the inclusion in the NP of the aforementioned aspects has raised the question of whether the biochemical composition of GR expands the scope of ABS, and whether derivatives are also included in it. These issues increase doubts about the actual extent of such a concept. For example, it may be questioned whether GR incorporate more components than functional units of heredity, and therefore raises the question of whether something has been excluded from the scope of ABS.

For the purpose of clarifying these doubts, the following sections first consider the concepts used in the Protocol to explain the term utilisation and try to understand them from a biological perspective. Following that, there is a review of the concepts of GR included in the CBD and the NP, and then a closing with an analysis of the notion of derivatives.

3.2.1 Understanding the concepts of genetic composition of GR and the biological composition of GR using notions from the field of biology

A. The genetic composition of GR

This term 'genetic composition' refers to the genetic information found in nuclear DNA (deoxyribonucleic acid).[17] According to the CBD, this information can be found in any material of plant, animal, microbial or other origin containing functional units of heredity. This might include, for example:

- Mitochondria, which are structures common to all cells (including reproductive cells) that are only inherited from the mother;[18]
- Viruses, which, despite having a genetic composition, cannot be classified as nuclear or mitochondrial because viruses have no distinct nucleus or mitochondria;[19]
- Bacteria, protozoa, fungi, and plasmids.[20]

[17] Bruce Alberts and others, Molecular Biology of the Cell (3rd edn, Garland Science 1994), 173.
[18] Rob Ogden and Adrian Linacre, 'Wildlife Forensic Science: A Review of Genetic Geographic Origin Assignment' (2015) 18 Forensic Science International: Genetics 152.
[19] Michael Madigan, John Martinko and Jack Parker, Brock Biología de Los Microorganismos (10 edn, Pearson Educacion 2003).
[20] Note that the term 'bacteria' was once conventionally employed (and is still sometimes used) in relation to all the prokaryotes (simple, unicellular organisms lacking a structured cell nucleus), but that it is now widely accepted that the Archaea (formerly known as archaebacteria) are in fact so fundamentally different as to constitute a completely separate domain. Along with the true bacteria and the eukaryotes (more complex organisms), this makes the three such domains in all.
Yoshizumi Ishino and Sonoko Ishino, 'DNA Replication in Archaea, the Third Domain of Life' in David Stuart (ed), The mechanisms of DNA Replication (InTech 2013).

B. The biochemical composition of GR

This concept may indicate that genes are fragments of DNA. Also, and more likely, it might be illustrating that any gene has a particular sequence of nucleotide pairs (or nitrogenous bases: adenine, guanine, thymine and cytosine), which codify to produce particular proteins (every three nucleotides codify to an amino acid, and proteins are long chains of amino acids).[21] For example, the proteins of milk, meat, and beans are the products of genes that are expressed so that cells of the cow or the bean plant produce these proteins. Currently, there are biotechnology techniques that allow the identification of a particular gene through its study and comparison with other genes from the same or different individuals. The economic interest in this kind of technology and its applications include, for example, the opportunity to create genetically modified organisms (GMOs) with special characteristics, such as exceptional levels of protein production.

There seems to be no difference between the notions of the genetic composition of GR and the biochemical composition of GR. Indeed, these terms are referring to GR from two different perspectives. The first points to genetic information, whereas the second is related to the uses and applications of GR. The intention to differentiate between the genetic and biochemical composition of GR in the NP may have been to make clear that the use of biotechnology forms part of the scope of ABS. As indicated earlier, some developed countries intend to put biotechnological products outside the scope of ABS. With that purpose, they opposed ABS for products obtained from the use of GR and TK in biotechnological processes.[22]

In this sense, the concept of biochemical composition of GR introduced by the NP does not expand the scope of ABS in the CBD. However, it should be noted that there are DNA Regions without genes that codify proteins. They contain short tandem repeats (STR) which have so far been used for the forensic analysis of remains, the identification of criminals, and paternity tests.[23] Apart from these uses, the commercial applications of such Regions are not yet clear. Nevertheless, this does not mean that new applications could not be realized in the future. In fact, this is an example of genetic material that does not contain functional units of heredity, but has practical application that has been left out of the scope of ABS. Based on this, it can be argued that only including the genetic material containing functional units of heredity limits the possibility of providers benefitting from the use of their resources; and it is for this reason that it could be argued that the concept of GR is a factor contributing to the small number of MATs.

3.2.2 Understanding the concept of GR in the CBD and the Protocol

The CBD has ascribed two primary meanings to GR. First, as the 'material from any

[21] Herve Seligmann (ed), *DNA Replication. Current Advances. Biochemistry, Genetics and Molecular Biology* (InTech 2011).
[22] Dwyer (n 5) 473.
[23] Mahmut Caliskan (ed), *Genetic Diversity in Microorganisms* (InTech 2012).

biological source where units of heredity are operating or having a function,'[24] i.e., as any biological material containing units of heredity. Second, as 'natural resources needed or used for their genetic material and not for their other attributes.'[25] Without adding something new, this second approach emphases the fact that all biological resources contain GR. For this reason, in practice, the difference between a biological resource and a GR is not the resource itself, but the way in which the resource is used.[26]

For example, traditional plant breeding is a technique used by farmers to improve resistance to pests and diseases and enhance the diversity and quality of agriculture and food products. It consists of the planting of certain varieties chosen through the observation of their particular characteristics. Farmers preserve the best seeds from the best plants from each planting for sowing, and continue to do this for generation after generation of the same plants. When doing this, farmers improve the characteristics they want in these plants. These seeds have the potential to be used as biological or genetic resources. When they are used for seeding, they are used as a biological resource. On the contrary, when the same seeds are used for research, for example, exploring the genetic characteristics that determine their resistance to pests and diseases, they are classed as GR. Allegedly, this is one aspect that makes monitoring and tracking the use of GR and TK difficult. As this example illustrates, the accessed resource is a seed, and it is the way in which that seed is used which determines whether it is regarded as a biological or genetic resource.

The set of definitions included in the CBD and the NP are the result of a long and hard negotiation process, demonstrating that ABS is a controversial topic. In the opinion of Rosell, the definition of GR is intentionally narrow and/or incomplete, so that valuable genetic information that could be obtained from materials other than those containing functional units of heredity has been left out of ABS transactions.[27] For Chaparro, the concept of GR has two general problems: (i) an artificial separation between biological and genetic resources;[28] and (ii) the use of classical concepts of genetics that were well established at the time of the CBD, which limit ABS to the use of molecular tools.[29]

In their opinion, such faults can significantly reduce the scope of ABS. On the one hand, it is argued that non-functional units of heredity must be included in the concept of GR because

[24] WIPO, Secretariat of the World Intellectual Property Organisation, 'Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions' (2015) WIPO/GRTKF/IC/30/INF/7, Annex 16.

[25] Greiber and others (n 2) 6.

[26] UICN, 'Recursos Biológicos Y Recursos Genéticos: El reto de diferenciarlos y regularlos' (2013) <https://www.iucn.org/es/content/recursos-biol%C3%B3gicos-y-recursos-gen%C3%A9ticos-el-reto-de-diferenciarlos-y-regularlos> accessed 6 October 2016.

[27] Monica Rosell, 'Access to Genetic Resources: A Critical Approach to Decision 391 "Common Regime on Access to Genetic Resources"' (1997) 6 RECIEL 274, 276.

[28] In other words, a biological resource is the expression of the genetic information it has. Thus, all biological resources contain genetic resources within themselves. Therefore, accessing to a biological resource also implies accessing to their genetic resources.

[29] Alejandro Chaparro Giraldo, 'Definiciones de Acceso a Recursos Genéticos en la Legislación Colombiana y sus efectos en la Investigación Científica' (2016) 21 Acta Biológica Colombiana 305, 305-306.

the constant advances of molecular biology mean that anything considered without function today may have a use tomorrow. An example of this is that GR, as resources, did not exist before biotechnology. More recently, this is the case with research on micro-RNAs, small non-coding sequences, which do not contain functional units of heredity or genes, but play an important role in controlling gene expression through complementary mRNA degradation.[30] For example, controlling gene expression is essential for the production of crops or animals with a high protein content. In this regard, such non-functional units of heredity are fundamental for the expression of the proteins which provide particular phenotypic characteristics to biological resources; in this example, crops or animals with a high protein content. On the other hand, the definition of GR in the CBD excludes any activity in genetics that uses conventional tools, such as hybridisation and selection.[31]

From a different point of view, scholars such as Tvedt and Schei consider that the concept of GR in the CBD can be interpreted in a broad sense. In their approach, the term 'functional' qualifies the object, thus scientific advances can link the concept of GR to 'the scientific and technological understanding of what is working or operating as functional units of heredity'. Additionally, they propose that functional 'could refer both to the genetic structure per se and to the information encoded in the DNA sequence (nucleotide) that can be screened and transferred into a digital form and become functional in a new, digital form.'[32]

Although this thesis agrees with the position of these authors that the CBD's concept of functionality could be interpreted in a broader sense to admit that 'having a role in controlling gene expression' actually suggests that so-called 'non-functional' units of heredity might themselves be regarded as 'functional' after all, it also acknowledges that when it comes to practice this flexibility is more difficult to achieve. Resistance to including new interpretations of GR has been addressed in Section 1.2.2 A of Chapter 1.

3.2.3 Derivatives

Derivatives are one of the non-agreed topics of ABS. During the Protocol's negotiations, developed countries requested that derivatives be outside of the scope of ABS, and proposed that the use of GR be considered as 'solely a commodity'.[33] As a result, derivatives remain outside the scope of ABS, and there were no modifications to the concept of GR. Nevertheless, developed countries argued that the distribution of benefits arising from the utilisation of derivatives could be possible if agreed and recorded in MATs by the parties involved in each

[30] Álvaro Pérez Quintero and Camilo López, 'Identificación de Elementos cisRegulatorios y Predicción Bioinformática de Factores de Transcipción Involucrados en la Regulación de miARNs en Plantas' (2013) 18 Acta Biológica Colombiana 107. Cited in: Chaparro Giraldo (n 29) 309.
[31] Chaparro Giraldo (n 29) 309.
[32] Morten Walløe Tvedt and Peter Johan Schei. 'The term 'genetic resources': flexible and dynamic while providing legal certainty?' (ch 2) in Sebastian Oberthür and G. Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, New York, 2014) 20.
[33] Jungcurt and others (n 7) 4-8.

particular case.[34] However, because derivatives are not within the scope of ABS, provider countries may experience difficulties in receiving the benefits derived from their use, even if they are recorded in MATs.

Derivatives are still a matter of dispute, and doubts have been raised as to whether their utilisation results in ABS obligations. For example, according to Tsioumani, the concept of derivatives in combination with Article 3 of the NP (which defines the scope of ABS), implies that derivatives are covered by ABS.[35] On the contrary, Schroeder considers that derivatives are excluded from the scope of ABS because, even if it is accepted that they are included, it is still necessary to establish how they relate to GR as well as the type of practices and innovations in which they can be used.[36]

Derivatives are a matter of ongoing concern and constant discussion. This is a possible indication that the market for products developed using derivatives of GR is bigger than the market of products developed from GR as described in the CBD, or at least, big enough to still be a matter of discussion between the Parties to the CBD.

3.3 Traditional Knowledge (TK)

The second element comprising the subject matter of the scope of ABS is TK. This can be understood as the knowledge developed by ILCs regarding the use and management of the biodiversity located in the territory in which they live. This is a complex concept with specific characteristics that interact with other notions such as traditional cultural expression and indigenous and local communities. With the aim of providing a better understanding of TK, the following sections explain its meaning and the meaning of its interrelated concepts.

3.3.1 Conceptualising TK

The legal approach to the protection of TK has been made through intellectual property rights (IPRs). This branch of the law, commonly split between industrial property and authors' rights/copyright, serves to protect intangible goods, typically associated with creation or innovation, by awarding property rights over them. IPRs can protect certain cultural manifestations, such as works of art, pieces of music, dances, and handicraft (via copyright, trademark, or design law), while certain types of knowledge concerning the use and

[34] Johannes Gnann and others, 'Summary of the Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 22-28 March 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 31 March 2010, vol 9, n 503), 5; CBD, Group of Technical and Legal Experts on Concepts Terms Working Definitions and Sectoral Approaches in the Context of the International Regime on Access and Benefit-Sharing, 'Compilation of Submissions by Parties, International Organisations, Indigenous and Local Communities and Stakeholders on Concepts, Terms, Working Definitions and Sectoral Approaches. Addendum. Submission from the Government of Japan' (2008) UNEP/CBD/ABS/GTLE/1/2/Add.1, 2.

[35] Tsioumani (n 6) 289.

[36] Schroeder (n 1) 206.

management of biodiversity may be protectable (patents, plant breeders' rights, or geographical indications).

However, it is not possible to protect all the cultural expressions of ILCs either exclusively as industrial property or via authors' rights/copyright law. That is why, for their protection, the adoption of two *sui generis* schemes were proposed: one similar to industrial property (relevant to scientific knowledge about biodiversity), and the other similar to authors' rights/copyright (relevant for creative expression).

This approach has apparently had a significant impact on the conceptualisation of TK. In order to make protection possible through the proposed twin-track *sui generis* systems, the cultural expression of ILCs has also been divided in two: the term Traditional Knowledge (TK) is only used to identify the knowledge about biodiversity, while the term Traditional Cultural Expressions is used for cultural expressions which are comparable to works of art. For ILCs, there is no such fragmentation of their culture. On the contrary, these communities have a holistic view of their world, where everything is a piece of an existent whole. Because of that, the fragmentation of their culture is artificial, and this may be a contributory factor in the difficulties facing the distribution of benefits derived from the use of TK.

However, as this thesis sets as its principal focus ABS concerning the use of TK associated with GR, traditional cultural expression and any interrelated subjects are excluded from this study, irrespective of the difficulty in separating them from TK.

3.3.2 The concept of TK in national laws

There is a significant variation in definitions and approaches to TK. There is also the absence of any consensus among laws, international instruments, and academics concerning the definition, scope, and content of TK, as previously stated in Section 1.2.1.b of Chapter 1.

At national level, conceptualisation about TK shows a similar approach to that used in the CBD. For example, some national laws consider TK as knowledge about biodiversity (Botswana,[37] Brazil,[38] and Peru[39]), which has been collectively created and held by indigenous or local communities (Botswana,[40] Brazil,[41] Burundi,[42] Bhutan,[43] and Peru[44]). A few countries also include traditional cultural expressions in the definition of TK (Burundi,[45] Bhutan,[46] and

[37] Botswana, Industrial Property Act, 2010, (Act No. 08 of 2010), Section 2.
[38] Brazil, Presidency of the Federative Republic of Brazil. Civil House. Legal Sub-Office. Law 13, 123, 2015, Article 2.
[39] Peru, Law No 27811 of July 2002, introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources 2002, Art. 2.
[40] Botswana (n 37) Section 2.
[41] Brazil (n 38) Art. 2.
[42] Burundi, Law No 1/13 of July 28, 2009, on Industrial Property in Burundi, Art. 2.
[43] Bhutan, The Biodiversity Act of Bhutan of 2003, Art. 3.
[44] Peru (n 39) Art. 2.
[45] Burundi (n 42) Art. 2.
[46] Bhutan (43) Art. 3.

Panama).[47]

Despite the many instruments defining TK from a variety of perspectives, it is possible to identify some common elements in these:

i. It involves knowledge about the use, management, and preservation of natural resources, in applications such as ethno-medicine, agriculture and water management;
ii. It is holistic, in the sense that TK is an inseparable part of the traditional community's worldview, which is perceived as a whole;
iii. It originates and is held collectively;
iv. It is dynamic, evolving over time;
v. It is learned through observation and experience;
vi. It is mainly recorded and transmitted orally, and sometimes it can be codified;[48]
vii. It is inter-generational because it is transmitted from one generation to the next, and it is intra-generational because it may be shared simultaneously by different age groups (grandfathers, sons, and grandsons for example);
viii. It has been exercised as perpetual property. TK has belonged to ILCs since the beginning of humankind;
ix. It could be disclosed[49] or undisclosed;
x. Depending upon the rules of each traditional community, TK may have different levels of disclosure inside the community: (i) 'public TK' shared by all community members, located in the community's public domain; (ii) 'specialised TK', which although not confidential, is not shared by all the community members, because it tends to relate to gender and/or role (for example midwives); and, (iii) 'secret TK' known and carefully preserved by a limited group within the community, (for example shamans) and shared only with the next keeper or group of keepers; and
xi. It is possible that more than one community shares the same TK: (i) owing to its

[47] Panama. Law No 20 of June 26, 2000, on Special System for the Collective Intellectual Property Rights of Indigenous Peoples for the Protection and Defence of their Cultural Identity and their Traditional Knowledge, Art. 1.

[48] 'Codified TK has been understood as TK, which is in some systematic and structured form, in which the knowledge is ordered, organised, classified and categorised in some manner. For example, in the field of traditional medicine, the WHO distinguishes between (i) codified systems of traditional medicine, which have been disclosed in writing in ancient scriptures and are fully in the public domain (e.g. traditional Chinese medicine disclosed in ancient Chinese medical texts); and (ii) non-codified traditional medicinal knowledge which has not been fixed in writing, often remains undisclosed by traditional knowledge holders, and is passed on in oral traditions from generation to generation.
Codified TK is different than the TK that has been recorded in written form and because it is accessible to the public, is considered for some to be in the public domain.' WIPO (n 24) Annex 4-5.

[49] Disclosed traditional knowledge refers to TK which is accessible to persons beyond the traditional community. Such TK might be widely accessible to the public and might be accessed through physical documentation, the internet and other kinds of telecommunication or recording. It also might be disclosed with or without the authorization of the ILCs who had created, developed and/or maintained the knowledge.
ibid Annex 10-11.

association with the use and management of natural resources located in a specific environment, it is possible that different communities located in similar environmental conditions can develop similar TK independently; and, (ii) ILCs usually share their resources and knowledge with each other.

3.3.3 The concept of TK in the CBD

The CBD establishes the rules for distributing the benefits arising from the use of TK associated with GR. Because of this, of all the definitions that exist for TK, the concept offered in the CBD has particular relevance for this analysis. According to the Convention:

> 'Article 8. Each Contracting Party shall, as far as possible and as appropriate:
> (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices.'

Two main elements are identifiable in this definition. The first refers to the knowledge itself and the second relates to the group of people that create or preserve this knowledge. First, TK is identified as the 'knowledge, innovations and practices…relevant for the conservation and sustainable use of biological diversity'. It may be deduced, therefore, that the Convention's scope is confined to TK concerning knowledge, innovation and practices associated with biodiversity. Second, TK is that which has been created and/or preserved by 'indigenous or local communities embodying traditional lifestyles'.

Despite the coexistence of these two elements, it appears that it is the nature of the community that creates and/or preserves the TK that prevails over the characteristics of this knowledge. In other words, it seems that the 'traditional' nature of the community creating TK is what characterises that knowledge as 'traditional knowledge', and allocates specific rights and economic expectations in favour of the communities having a 'traditional' lifestyle. In other words, according to the CBD, the opportunity to claim property rights over TK and compensation for its use is dependent on being considered as an indigenous or local community embodying a 'traditional' lifestyle.

The 'traditional lifestyle' is apparently the most important aspect of the concept of the CBD, since this characterises a community as having the right to benefit from the use of their TK and the knowledge produced by them as 'traditional knowledge'. Consequently, in the terms of the Convention, TK is that which has been created or preserved by ILCs having a traditional lifestyle. In addition, the CBD contains no definition or indication of any special characteristics of such communities beyond the mention of their traditional lifestyles. This is

something to be resolved by the Parties to the CBD through their national laws. Section 6.2 of this chapter explains the way in which the concept of ILCs may be understood.

4. The structural elements of ABS

Access is conditional on the prior informed consent (PIC) of the Party providing the resource. The terms for accessing and distributing the benefits arising from the utilisation of the accessed resource must be recorded in mutually agreed terms (MATs). This is the very basis of ABS—a system founded on the idea of asking for permission before using someone else's property, with the consequent duty of sharing with the owner the benefits resulting from the utilisation of their property. In order to understand if the conceptualisation of PIC and MAT is a factor which adds to the difficulties of realising ABS, a more detailed explanation of the meaning of its elements is provided below.

4.1 Prior Informed Consent (PIC)

4.1.1 The origins of the concept of PIC

The concept of PIC was originally derived from medical ethics, which recognises the right of patients to decide whether or not to undergo a medical treatment, for which they should be fully informed about the risks and benefits. PIC has evolved from this concept to become the required condition for accessing GR and TK which leads to utilisation, and the consequent distribution of benefits derived from such utilisation.

For ILCs particularly, this concept has evolved to integrate the general principle of participation in decision-making and involvement in the formulation, implementation, and evaluation of works and programs affecting them.[50] In this regard, it has been argued that PIC is a principle that functions as protective of and instrumental to the enjoyment of the rights recognised in favour of such communities.[51] This could also be the reason why, for many authors, PIC derives from the same right of self-determination,[52] which is understood to be the

[50] ibid Annex 30-31.

[51] James Anaya, 'Technical Review of Key Intellectual Property-Related Issues of the WIPO Draft Instruments on Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions' (2016) WIPO/GRTKF/IC/29/INF/10, Annex 3.

[52] In this regard, the International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1996, entered into force 03 January 1976) 993 UNTS 3 (ICESCR), states in Article 1.1 that: '[a]ll peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development', and in Article 1.2 that '[a]ll peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law. In no case may a people be deprived of its own means of subsistence.' Furthermore, the ILCs' right to determine their development is articulated in Article 31 of the United Nations Declaration on the Rights of Indigenous Peoples (adopted 13 September 2007), which states that 'indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge

founding principle of indigenous peoples' rights[53] as well as a collective human right. As a part of the right to self-determination, which derives from the right to autonomy or self-government, ILCs have the right to manage and regulate the use of their GR, TK, and traditional cultural expressions, in accordance with their customs, laws, and traditions. The exercise of such a right implies that they can determine to what extent and under what conditions these resources can be accessed and used by others,[54] and they have the right to withdraw their consent. (Some examples of this are provided in Section 2.1.1 of Chapter 1.)

In addition, PIC from countries of origin of GR has been linked to the exercise of sovereign rights.[55]

4.1.2 The concept of PIC

PIC, sometimes referred as to 'free, prior and informed consent' (FPIC), is usually found as a right or principle in international instruments in the environmental field. Within the particular frame of the CBD, access is conditional on PIC granted by the party providing GR and/or TK. Because of this, PIC has been understood as the permission granted by the right holder of GR and/or TK, given before access, and conducted with the aim of using the resource accessed.

Because PIC is considered as the mechanism for assisting the achievement of the objectives of the CBD, its correct implementation is of great significance.[56] However, the CBD did not provide a solution for cases of access without PIC. Although it could be claimed that those situations can be addressed by the mechanism proposed in Article 10 of the Nagoya Protocol, as mentioned earlier, the establishment of such a mechanism was aimed at solving situations in which PIC could not be obtained for reasons associated with accessing GR and TK in transboundary situations, or because the resources were accessed before the CBD came into force.

of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.'

[53] Tara Ward, 'The Right to Free, Prior, and Informed Consent: Indigenous Peoples' Participation Rights within International Law' (2011) 10 Northwestern Journal of International Human Rights 54, 55.

[54] Anaya (51) Annex 2-3.

[55] Nagoya Protocol (n 12).

'Article 6. Access to Genetic Resources:

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.'

[56] Stuart Harrop, '"Living in Harmony with Nature"? Outcomes of the 2010 Nagoya Conference of the Convention on Biological Diversity' (2011) 23 Journal of Environmental Law 118, 127.

4.1.3 PIC obtained from ILCs

The NP establishes that PIC for accessing TK have to be obtained from ILCs, and that they have the right to determine the competent authority for doing so. However, as this right was not completely clear in the CBD, and almost twenty years elapsed between the CBD (1992) and the NP (2010), some countries determined, for example, that this PIC could be obtained from the ILC that owns the knowledge, or from a national authority on its behalf.[57] While today it seems to be clear that PIC should be granted only by ILCs,[58] it should be remembered that ILCs can exercise those rights to the extent they are recognised in the national law of the country in which they live.

4.1.4 PIC and the Human Rights of ILCs

PIC is linked to the human rights of ILCs. This is because the concept of PIC is also contained in several international human rights instruments[59] in which it is associated with cultural rights and the right to non-discrimination.[60] The latter recognises ILCs' 'inherent and prior rights to their lands and resources' that are derived from 'their legitimate authority to require that third parties enter into an equal and respectful relationship with them, based on the principle of informed consent.'[61] In this regard, PIC further supports the recognition of the property rights of ILCs over their lands as well as the natural resources therein. The latter is a consequence of the acceptance of their ancestral presence in the territories they occupy, and the consequent right to participate in the political and economic life of the states in which they

[57] For example, this is the case of the Decision No 391 of 1996, establishing the Common Regime on Access to Genetic Resources of the Andean Community of Nations, whose paragraph 2 of Article 35 establishes:
'(…)
The annex shall be signed by the supplier of the intangible component and the applicant for the access. It may also be signed by the Competent National Authority, in accordance with the provisions of national law of the Member Country. If that annex is not signed by the Competent National Authority, it shall be subject to the suspensive condition referred to in Article 42 of this Decision. (…)' (Emphasis added)

[58] This certainty comes from the text of the Nagoya Protocol and case law of the Inter-American Court of Human Rights: Case of the Saramaka People v Suriname (Preliminary Objections, Merits, Reparations, and Costs) Inter-American Court of Human Rights Series C 172 (28 November 2007) <http://www.corteidh.or.cr/docs/casos/articulos/seriec_172_ing.pdf> accessed 13 January 2015

[59] For instance, the Universal Declaration of Human Rights (UDHR); the International Covenant on Civil and Political Rights (ICCPR); the International Covenant on Economic, Social and Cultural Rights (ICESCR); the Convention on the Elimination of Racial Discrimination; the United Nations Declaration on the Rights of Indigenous Peoples; and the International Labour Organization Convention 169.

[60] The Inter-American Court of Human Rights has also made recognition of PIC on the basis of ancestral occupation of the lands. It can be found, for example in the Case of Saramaka People v. Suriname and the Case of the Kichwa Indigenous People of Sarayaku v. Ecuador.
Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, Working Group on Indigenous Populations, Twenty-second session, 19 -13 July 2004, 5.

[61] ibid

live.[62] In the same way, the NP recognises the right of ILCs to grant PIC before accessing their TK[63] and GR.[64]

Along the same lines, the concept of PIC has also evolved from the right to self-determination at the International Labour Organisation (ILO). In this regard, the 1989 ILO Convention 169 considers PIC as a mechanism to ensure that ILCs can fully and effectively enjoy their collective rights to property over lands and resources, autonomy, participation, and cultural identity. Moreover, because the full enjoyment of the right to self-determination requires consultation and participation, both the consultation process for obtaining PIC, as well as its inclusion in an agreement (MAT) needs to be reached under the following conditions: (i) the application of ILCs' customary laws, procedures and protocols; (ii) good faith; and (iii) guaranteed full participation of ILCs through their truly representative authorities.[65]

4.1.5 The PIC elements

Proposals for the specific elements of a PIC mechanism are found in a number of instruments. These include, for example, the 2005 International Workshop on Methodologies regarding Free, Prior and Informed Consent and Indigenous Peoples of the Permanent Forum on Indigenous Issues,[66] the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization (the Bonn Guidelines),[67] the Manual of the ILO Convention 169,[68] and the Akwé: Kon Guidelines.[69] They all confirm that PIC needs to be:

i. Prior;
ii. Informed;
iii. In good faith;

[62] Inter-American Court of Human Rights (n 53); Case of the Kichwa Indigenous People of Sarayaku v Ecuador (Merits and Preparations) Inter-American Court of Human Rights Series C 245 (27 June 2012) <http://corteidh.or.cr/docs/casos/articulos/seriec_245_ing.pdf> accessed 13 January 2015.
[63] Nagoya Protocol (n 15), Article 7.
[64] ibid, Article 6.2
[65] Parshuram Tamang, 'An Overview of the Principle of Free, Prior and Informed Consent and Indigenous Peoples in International and Domestic Law and Practices' (Presented at the Workshop on Free, Prior and Informed Consent and Indigenous Peoples, organized by the Secretariat of UNPFII, 17-
19 January 2005,UN Headquarter, New York, USA).
[66] Permanent Forum on Indigenous Issues, 'Report of the International Workshop on Methodologies Regarding Free, Prior and Informed Consent and Indigenous Peoples' (Economic and Social Council, United Nations 2005) E/C.19/2005/3.
[67] CBD, Secretariat of the Convention on Biological Diversity, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization (2002).
[68] International Labour Organization, 'ILO Convention on Indigenous and Tribal Peoples No. 169: A Manual' (1989).
[69] CBD, Secretariat of the Convention on Biological Diversity, Akwé: Kon Voluntary Guidelines for the Conduct of Cultural, Environmental and Social Impact Assessments Regarding Developments Proposed to Take Place On, or Which Are Likely to Impact On, Sacred Sites and on Lands and Waters Traditionally Occupied or Used <https://www.cbd.int/doc/publications/akwe-brochure-en.pdf> accessed 20 February 2015.

iv. Without coercion, intimidation, or manipulation of the relevant information; and,
v. Obtained from the competent national authority(ies) for the GR,[70] and from the traditional authority(ies) for the TK in accordance with the ILCs' customary law,

otherwise it is not possible to confirm that the provider has actually expressed their will.

These concepts are explained as follows:

A. Prior

As a requirement, prior means that the consent of the provider should be obtained before accessing their GR or TK. This is because PIC was initially developed from a principle that those giving an authorisation have the right to be informed before giving their consent about the potential damage, harm, or threat caused by the development of determined activities. In this sense, prior means not only that such information must be provided to give consent, but also that the user gives their consent through an affirmative act based on the information delivered by the user. Both the consent and all the relevant information have to be communicated before access.

B. Informed

The user has to communicate all the required information so that the provider can decide with a full understanding of the conditions and consequences involving access. The importance of the information provided by the user is of such magnitude that PIC can be invalidated when relevant information regarding access has been omitted in order to obtain consent.[71]

[70] For the cases when GR are accessed through an *ex-situ* conservation centre, the Bonn Guidelines suggest that PIC could be obtained from the competent national authority, or from the body governing the *ex-situ* collection, under the understanding that the resources were acquired under the CBD rules or before its issuance.
CBD (n 67) Art. 32.

[71] The minimum information required includes:
The nature, size, pace, reversibility and scope of any proposed project or activity;
The reason(s) for, or purpose(s) of, the project and/or activity;
The duration of the project/activity;
The locality of areas that will be affected;
A preliminary assessment of the likely economic, social, cultural and environmental impact, including potential risks; and fair and equitable benefit-sharing in a context that respects the precautionary principle;
Personnel likely to be involved in the proposed project (including indigenous peoples, private sector staff, research institutions, government employees and others); and procedures that the project may entail.

C. In good faith

This characteristic refers to the process of obtaining PIC. During this process, in addition to the need to deliver all the information regarding access, users also have to provide clear and accurate information about the intended use of the resource, including its possible transfer to third parties. PIC should be sought far enough in advance to give states, and particularly ILCs, enough time to understand the conditions for the access, as well as its possible impacts on their traditional lifestyles and the environment. Because for ILCs PIC relates to other fundamental rights such as self-determination, cultural identity, autonomy and participation, granting authorisation also involves the right to refuse and withdraw consent.[72]

D. Obtained from the competent authority

According to the CBD, PIC should be obtained from the Party providing the resource, otherwise determined by that Party. This is the country of origin of the resources, or the Parties that have acquired the resources, according to the CBD. The NP has established that, in cases where national legislation provides them with such a right, ILCs can grant PIC for access to their TK and GR. An explanation about the identity of the provider of GR is set out in Section 6.1 of this chapter. In the same way, a description of ILCs is provided in the Section 3.4

4.1.6 PIC in Article 10 of the Nagoya Protocol

A contradiction may result from the content of Article 10 NP. It states that Parties shall consider the need for and method of a GMBSM to address the distribution of benefits derived from the utilisation of GR and/or TK for which it is not possible to grant or obtain PIC.

Reading this Article in isolation could lead to two possible conclusions: (i) that GR and TK can be accessed and used without conducting PIC, or (ii) they can be accessed without obtaining the consent of the provider by claiming that it was not possible to obtain. However, from a comprehensive reading of the CBD and the NP it can be seen that the proposed mechanism in the Protocol was not meant to allow or legalise access without PIC.

Accepting otherwise would be a violation of the sovereign rights of provider countries over their GR and ILCs' rights over their TK. It should be kept in mind that the authority to determine access, including decisions about which resources or the conditions under which some of them can be accessed without PIC, rests in the country of origin of GR and TK.

[72] This right has been recognised in some national legislation. A case in point is the Biological Diversity Act of 2000 of the Bolivarian Republic of Venezuela, in which Art. 43 acknowledges such a right in the following terms: 'The State recognises local communities and indigenous peoples have the right to refuse consent to authorise the collection of biotic and genetic materials, access to traditional knowledge, and the development of plans and projects of biotechnological character on their territory, if the information in terms of utilisation of resources and the benefits that could be obtained is not provided in advance. Local communities and indigenous peoples may also require the elimination of any activity when demonstrated that it affects their cultural heritage or biological diversity.'

In addition, as explained in Section 3.1.8 of Chapter 3, Article 10 NP resulted from discussions about the use of GR accessed before the CBD came into force and GR located beyond national jurisdiction. It is therefore in this context in which the impossibility of granting or obtaining PIC should be understood.

4.2 Mutually Agreed Terms (MATs)

Mutually Agreed Terms (MATs) is the agreement that governs ABS of GR and TK. It should be contained in a written document which specifies the conditions for accessing and using the authorised GR and TK. Its main provisions typically contain information about:

i. Obligations for providers and users;
ii. The type, amount and place where the resources can be accessed from (collected);
iii. Rules and conditions for the use of the resources, including ethical considerations and whether the user can share the accessed resources with third parties or save samples for further research;
iv. Considerations about the customary use of GR and TK by ILCs;
v. Rules for the use of IPR and licences for use;[73]
vi. Financial compensation for using the resources;
vii. Transfer of technology; and
viii. Other agreed obligations between the parties.

The Bonn Guidelines also set out the basic requirements for MATs and contains a list of typical MAT provisions, possible forms of benefits and a pro-forma MAT. From these, it can be implied that MATs involve a negotiation between providers and users of GR and TK. Consequently, and contrary to claims by some,[74] MATs cannot simply be assimilated with a material transfer agreement (MTA) typically used by *ex-situ* collections when providing samples of biological materials. In fact, the Executive Secretary of the Convention has noted that contracts are the most common way of recording MATs, even before the CBD and other laws governing ABS came into force.[75] As the name indicates, an MTA is an agreement involving the handing-over of biological material. It does not necessarily, and does not normally, include a distribution of benefits with the country of origin of these resources.[76] In contrast, the main

[73] CBD, (n 67) Arts. 42 and 43.
[74] Greiber and others (n 2) 9.
[75] CBD, Secretariat of the Convention on Biological Diversity, 'Addressing the Fair and Equitable Sharing of the Benefits Arising out of Genetic Resources: Options for Assistance to Developing Country Parties to the Convention on Biological Diversity' (1998) UNEP/CBD/COP/4/22, para 32.
[76] Kate Davis and others, 'An Access and Benefit-Sharing Awareness Survey for Botanic Gardens: Are they prepared for the Nagoya Protocol?' (2015) 98 South African Journal of Botany 148, 153-154.

objective of a MAT is to record the conditions about access and distribution of the benefits derived from the utilisation of GR and TK that have been agreed.

5. PIC and MAT in short

To summarise, access to GR and TK is conditional on PIC, and where granted, it must be recorded in MATs. The primary aims of PIC and MAT are to: (i) authorise and determine the conditions for access; (ii) set out the rules for the utilisation of the resources, including the authorisation (or not) of subsequent uses; and (iii) establish the conditions for the distribution of benefits. Finally, owing to the desirability that PIC and MATs should be recorded in written form, authors such as Torres and Chávez consider that a non-recorded PIC or MAT do not have any legal validity.[77] However, although this effect is not considered in the CBD or the NP and, therefore, it cannot be taken for granted; it cannot be denied that a recorded PIC and MAT gives greater legal certainty to the contracting parties.

Taking all the above into account, it can be concluded that PIC and MAT as such do not pose limitations on ABS. The limitations stem instead from the system's design, of which PIC and MAT constitute foundation elements whereby the distribution of benefits occurs.

6. The ABS obligations

6.1 Facilitated access

ABS is a right built in relation to access to GR and associated TK. The reference to this is in Article 15 CBD, which enacted the ABS system under the subheading 'Access to Genetic Resources', and later in the title of the NP 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation' (emphasis added). Article 15 CBD is the core ABS provision, to which Articles 8j, 16, 18, and 19 are related, and the NP is a legally-binding supplementary agreement to the CBD in the matter of ABS.

Despite the utilisation of the word 'access' throughout the CBD and the NP, there is no definition of 'access' in these instruments. Nonetheless, the Convention establishes that: 'Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties (…)' (Article 15.2) (emphasis added). The authority to determine access to the resources and to decide when a use is environmentally sound is left to the discretion of the providing Party (Article 15.1). At first glance, it could be assumed that the primary aim of Article 15.2 is the promotion of biodiversity protection through increasing the opportunity for providing countries to achieve more benefits, given that a facilitated access will produce greater benefits. However, maybe because the Convention does not include an effective system of compliance with the ABS obligations,

[77] Ricardo Torres and Juanita Chávez, *Posibles Elementos Para La Protección Del Conocimiento Tradicional En Colombia*, Instituto Alexander von Humboldt (2003), 17.

the benefits derived from the use of the resources are difficult to obtain (as the number of MATs in Chapter 1 seem to show). Under these circumstances, the practical effect of the obligation to provide facilitated access to GR is that users can easily have access to these resources, while enforcement of the obligations deriving from it is very difficult to achieve.

With regard to the content of Article 15.2, Greiber and others argue that the logic behind it is that fair and equitable sharing of benefits can only be realised after access to GR and TK has actually been granted.[78] However, while it is true that access is often a required condition for the utilisation of the resources,[79] it is also the case that the motivation for allowing facilitated access is precisely the benefit received in return. Following this logic, what would ensure facilitated access is the certainty of the distribution of benefits and not vice versa. Seemingly, herein lies another flaw of the ABS system: there is nothing in the CBD or the NP to ensure the distribution of benefits once a resource has been accessed.

In the absence of a definition of 'utilisation' in the CBD and the NP, some countries have developed their own concepts in their national laws on ABS. As noticed by Glowka,[80] access is generally defined through the use of terms such as 'prospecting', 'bioprospecting', and 'biodiversity prospecting'. All refer to the physical possession of GR that enables their use in scientific, economic, and other applications. As ABS has been designed to conduct access *in-situ*, it should be taken into account that such concepts leave out the dynamics of accessing GR and TK in *ex-situ* conditions, which have distinct features from access *in-situ*.

The possibility of gaining access to GR *ex-situ* without the need to follow an ABS process affects the opportunity for states to control the use of their resources. For this analysis, the practices developed by scientists regarding this kind of access are of great importance. As demonstrated by Davis and others, accessing GR in *ex-situ* collections is an activity usually accompanied by the sharing of the information obtained after conducting research over the accessed resources. In ABS terms, the *ex-situ* collection usually benefits from the disclosure of scientific data obtained from the accessed resource in exchange for allowing access to the resources they store.[81] Nowadays, genetic information has progressively gained in importance for researchers' activities. The main consequence of this is that access *in-situ* is needed less and less as scientists can make their discoveries using the information already available in databases, using technologies such as synthetic biology.[82] Thus, under the CBD logic, not only access *ex-situ* but also access to genetic information and its utilisation in new biotechnological fields are excluded from the ABS scope.

In addition, difficulties in determining what access is, or when it occurs, continue to be a cause of controversy among providers and users of these resources. These problems are

[78] Greiber and others (n 2) 8.
[79] It should be remembered that technologies such as the synthetic biology allow the utilisation of GT without physically accessing the resource.
[80] Lyle Glowka, 'Emerging Legislative Approaches to Implement Article 15 of the Convention on Biological Diversity' (1997) 6 RECIEL 249, 250.
[81] Watanabe (n 11) 548.
[82] ibid 549.

derived from the particular conditions surrounding access rather than in the lack of acceptance that access is the physical possession of the resources, or that (at least initially) it is required for developing research activities. The factors involving access activities, such as the identity of the provider, when the resource is accessed from an *ex-situ* conservation centre, whether the resources were acquired by the *ex-situ* centre according to the CBD, and the kind of intended uses of the resources (whether the resource has been used as a biological resource or as a GR) are some of those preventing ABS agreements when GR and TK are used.

Determining access to TK has its own obstacles. These can be divided into three main groups. The first is that TK has not been properly documented. It may, therefore, be difficult to: (i) link TK with one or more specific ILCs; and (ii) find TK in a prior art search. The second is directly related to the first. Neither the CBD nor the NP suggest how to conclude ABS transactions over shared resources, which is a common characteristic of TK, leaving this problem to the countries for a solution. The difficulties regarding access to TK in these circumstances are associated with situations in which: (i) one ILC authorises access to a TK while at the same time another ILC opposes access to that TK; and/or (ii) ILCs sharing the same TK who are not the provider claim that they are also entitled to compensation; and finally, (iii) the assumption that almost all TK is in the public domain. This last situation results from the erroneous idea that everything which is publicly accessible is in the public domain and, consequently, can be freely accessed, used, and appropriated. Under these conditions TK has been accessed and used without the consent or knowledge of the ILCs to whom the TK belongs. Because of this, a distribution of benefits from the use of such TK has probably not yet occurred.

Despite the difficulties in determining 'access' as a subject matter, provider countries have the responsibility to provide for: (i) legal certainty, clarity and transparency of their ABS domestic legislation and regulatory requirements; (ii) fair and non-arbitrary rules and procedures; (iii) clear rules and procedures for PIC and MATs; (iv) the issuing of a permit or equivalent as evidence of the decision to grant PIC and of the establishment of MATs; and (v) notification to the ABSCH about the access activities carried out by them (Article 6.3 NP). This means that countries will determine the content and scope of the term 'access' at their own discretion and according to their particularities and needs.

Consequently, heavy burdens are imposed on both providers and users of GR and TK. Providers have to fill in the gaps of the CBD through their national laws, which creates multiplicity of rules and approaches to ABS. For their part, users have to know, understand, and follow all the different rules and approaches of providers. Needless to say, this problem would be better addressed with a mechanism with some level of international reach, such as the GMBSM, rather than seeking compliance through the creation and application of disparate national laws.

6.2 The Fair and Equitable Sharing of Benefits

Bioprospecting is the search for valuable components in biological resources that could potentially lead to marketable products. This activity has value in industries such as medicine, pharmacology, cosmetics, and agriculture. Megadiverse countries are a good place for bioprospecting due to their wide variety of natural resources. Megadiverse countries are usually developing countries which often lack the scientific research capacity to conduct their own bioprospecting over their biodiversity and do not have enough technology development to make use of it. On the other hand, the ILCs from megadiverse countries have developed the knowledge about how to use and manage the natural resources located in the territory in which they live. Such TK is also important for bioprospecting activities. It helps to identify the resources with potential uses, without the need for conducting research over all the natural resources located in a particular area, instead observing how they are utilised by ILCs. In practical terms, this means that TK helps to reduce bioprospecting costs.

For a long time, industrialised countries have conducted research and development on the biological resources of developing countries. Sometimes, the development of such products has included TK. For many years, these activities were conducted without sharing the benefits arising from the use of the resources and knowledge from the developing world. Over time, the provider countries of these natural resources, together with the ILCs, have achieved recognition of their rights over such biodiversity and TK, respectively. This acknowledgement, in turn, has led to recognition of their right to receive compensation for the use of their resources. Furthermore, it has been established that such a distribution of benefits needs to be done in a fair and equitable way.

However, these terms are not defined in the CBD or the NP. Similarly, and even though some rules about the proportion of benefits that should be distributed have been found in the laws analysed in Chapter 2, no reference to what a 'fair and equitable distribution of benefits' might be could be found. This section builds on these concepts using notions from international law and, particularly, form the international agreements for the use of resources in transboundary situations. In doing so, the notion of what is fair and equitable in the CBD, the NP, and in transboundary situations is explained. This thesis argues that the term 'fair and equitable' has the same meaning as that in international law.

6.2.1 The notion of 'Fair and Equitable' in International Law

The concepts of fairness and equity are usually interchangeable, and traditionally have been associated with the idea of justice. In spite of this, it is possible to distinguish different approaches to these concepts. For example, fairness and equity are considered by Soltau as deep-rooted concepts in human relations, and invoked when decisions involve far-reaching social, economic, and environmental decisions.[83] His hypothesis can be verified by the common

[83] Friedrich Soltau, Fairness in International Climate Change Law and Policy (CUP 2009), 2.

use of these concepts in many international environmental agreements for sustainable development.[84] In addition, it has also been argued that the legal concept of equity 'is a general principle directly applicable as law,'[85] which, in international law, has two routes of entry. The first is via general principles of law frequently referred to as *equity infra*, *praetor,* and *contra legem*. The second is its application in other principles such as good faith, unjust enrichment, abuse of rights, estoppel, and acquiescence.[86]

In international environmental agreements, the notions of fairness and equity have been used to provide a 'commonly accepted operational framework for addressing cooperation, compliance, and the appropriate use of international transboundary resources.'[87] Accordingly, it could be argued that because the CBD is an agreement in the environmental field it is embedded within the same principles, and that their inclusion is intended to achieve the aims set out above. Furthermore, the use of the principles of 'equity and equitable' by international courts and tribunals as a part of general international law has been interpreted by Gourgourinis as an indicator of the common use of these concepts in the international arena.[88]

One particularly useful example of the application of the notion of 'equity' in international law can be found in the 1997 UN Watercourses Convention and the earlier ILA Helsinki Rules, since they illustrate the possibility of formally identifying and itemising the kinds of consideration that may be relevant to its interpretation and application in a specific context.

6.2.2 The notion of 'Fair and Equitable' in the CBD and the Protocol

A possible understanding of the concept of fair and equitable distribution of benefits in the CBD has been proposed by Koester.[89] According to him, this notion is the expression of the principle of intra-generational equity. He argues that the obligation of users to share the benefits arising from the use of GR and TK has its origins in the idea that all people have the right to benefit from the use of natural resources. He links the principle of intra-generational equity with the idea that conservation of biological diversity is a common concern of humankind. He argues that the fair and equitable sharing of benefits relates to the use of

[84] For instance, the United Nations Convention on the Law of the Sea (LOSC), the United Nations Conference on Environment and Development (UNCED), the United Nations Millennium Development Goals (UNMDG), the United Nations Framework Convention on Climate Change (UNFCCC), the United Nations Conference on Sustainable Development (UNCSD), and the CBD.

[85] Case Concerning the Continental Shelf. Cited in: Anastasios Gourgourinis, 'Equity in International Law Revisited (with Special Reference to Fragmentation of International Law)' (2009) 103 Proceedings of the Annual Meeting of the American Society of International Law 79, 80.

[86] ibid

[87] Brooke Campbell and Quentin Hanich, 'Principles and Practice for the Equitable Governance of Transboundary Natural Resources: Cross-Cutting Lessons for Marine Fisheries Management' (2015) 14 Maritime Studies 1, 3.

[88] Gourgourinis (n 85) 80.

[89] Veit Koester, 'The Convention on Biological Diversity and the Concept of Sustainable Development: The Extent and Manner of the Convention's Application of Components of the Concept' in Michael Bowman, Peter Davies and Edward Goodwin (eds), *Research Handbook on Biodiversity and Law* (Edward Elgar Publishing 2016), 280.

biodiversity in connection to the right of everyone to benefit from such resources.[90] In this sense, it can be understood that distributing the benefits derived from the use of GR and TK will help their conservation, which ultimately could ensure that all can benefit from them.

While it is not possible to conclude that the drafters of the CBD used the principle of intra-generational equity to support benefit-sharing, the link between the preservation and sustainable use of biodiversity as a common concern, along with the idea that a distribution of benefits would help to achieve that objective, is clear in the CBD.

Additionally, the NP establishes the obligation to share with ILCs the benefits of the use of their TK. From this, it seems clear that benefit-sharing is intended not only to preserve biodiversity but also to protect the people directly involved with the conservation and sustainable use of biodiversity.

Notwithstanding the above, it is still unclear as to what is meant by 'fair and equitable distribution of benefits'. With the aim of finding out how this concept should be understood, the next sections attempt to provide clarity on this issue.

6.2.3 Fairness in ABS

In relation to ABS, fairness is connected with the unjust situation previously faced by provider countries and ILCs, in which it was considered that they had no compensation rights for the use of their resources. This situation was considered unjust, and its amendment logically implied the opposite, i.e., the recognition of a compensation right. This approach, supported by discussions regarding farmers' rights within the FAO, helped to gain acceptance of the distribution of benefits as an obligation on the Party using GR and TK. Legally, such a right is derived from the sovereign rights of the provider countries over their natural resources and the acknowledgement of the contributions made (in past, present, and future) by ILCs (and farmers) for the preservation and sustainable use of biodiversity (and food security).

6.2.4 Equity in ABS

For Tvedt and Young, in ABS contexts equity is connected: (i) with the amount of money that should be shared by the use of GR and TK, for the historic contribution of these resources; (ii) with the question of to what extent the properties of a given GR are the reason that the innovation or product was developed; and, (iii) with the contribution made that enabled the existence of a particular GR or ecosystem.[91]

Additionally, the Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) notes that while GR has been generally considered as raw material, TK valuation should be different. For them, TK's valuation could be determined either by its economic value to industry (on the basis of the particular needs of industries, availability of the knowledge and

[90] ibid
[91] (n 12) p. 88

its usefulness), or by its contribution to the greater good of humanity in biodiversity conservation (TK's role in conservation and sustainable use of biodiversity).[92]

For his part, Millum considers that where multiple parties contribute to the creation of some social surplus, a fair share of benefits should reflect this contribution. He maintains that the economic value of GR and TK should be calculated on the basis of how much people are willing to pay for them, which can be done by modelling the market. In his opinion, this will allow fair transactions without the need to determine a principle of fairness.[93] From a different perspective, but with a similar meaning, for the WIPO, an equitable remuneration is 'the remuneration of certain acts carried out in respect of a work or an object of related rights in an amount and in a manner consistent with what may be regarded as normal commercial standards in case of authorization of the same act by the owner of a copyright or related rights.'[94] Despite this concept specifically referring to cases in which an economic right has been reduced to a right to remuneration, the reference to 'normal commercial standards' is used to indicate that an equitable remuneration is that which is established according to the market.

It seems clear from the above that, despite the acknowledgment of the countries' and ILCs' contributions to preservation and sustainable use of biodiversity, the proposals of a 'fair and equitable distribution of benefits' apparently only consider the value that GR and TK in the market. This may be a consequence of the difficulties in the measurement of the intrinsic value that GR and TK have. For this reason, it could be argued that the minimum amount of money to distribute should be the economic value of GR and TK, which can be determined by calculating the market.

Nevertheless, as explained in the following section, although the intrinsic value of GR and TK may be difficult to establish, a fair and equitable distribution of benefits would be more likely to be achieved if the principles used in international law for the use of transboundary natural resources are applied.

6.2.5 The Notion of Fair and Equitable Benefit-Sharing in Transboundary Situations

Article 10 NP apparently confirms the need for a GMBSM to address the fair and equitable sharing of benefits derived from the utilisation of GR and TK in transboundary situations. However, as set out by Campbell and Hanich, the best-written intentions have been poorly converted into effective practice when sharing the benefits in transboundary situations.[95] For these authors, the main factor affecting such a distribution of benefits lies in

[92] CBD, Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity, 'Development of Elements of Sui Generis Systems for the Protection of Traditional Knowledge, Innovations and Practices' (2007) UNEP/CBD/WG8J/5/6, 9.
[93] Joseph Millum, 'How Should the Benefits of Bioprospecting be Shared?' (2010) 40 The Hastings Center Report 24, 28.
[94] WIPO (n 24) Annex 13.
[95] Campbell and Hanich (n 87) 1.

the ability to relate key human social interactions to conservation outcomes. A key social interaction is the way in which the stakeholders perceived fairness and equity. This perception is affected by asymmetries in wealth, power, capacity, and need.[96] Consequently, it is possible that different stakeholders have different perceptions of fairness and equity in the distribution of benefits.

The use of natural resources in transboundary situations is also an issue largely addressed by international law. In this regard, the core elements in transboundary natural resource policy include responsibility, rights, and justice. Responsibility is associated with established international legal obligations, which requires states to apply other international principles such as good faith. Rights are the rules that interact with the responsibility to assist in procedural and substantive interpretations of what is fair in a given context. Finally, justice is concerned with the distributive aspects of social justice.[97]

To Rawls, distributive justice supports the notion of 'fair-sharing', 'equitable utilisation', and 'fair equality of opportunity'.[98] Moreover, distributive justice has been considered to be related to individual well-being[99] and to be a guide in the procedural relationship between the equity of a decision-making process and the perceived equitability of its outcome.[100] On this basis, Campbell and Hanich argue that distributive justice provides essential structural underpinnings for the negotiation of the use of transboundary resources. For them, an 'equity process' could be integrated into regular negotiation processes by requiring negotiating stakeholders to answer procedural questions about the conceptual framing elements of responsibility and rights.[101] In other words, for these authors, equity in the distribution of benefits in transboundary situations could be achieved by respecting the recognised responsibilities and rights of the different stakeholders involved. Consequently, ABS negotiations should include the concepts and general principles of 'fair and equitable' in international law, and the particular considerations regarding rights and obligations related to the use of transboundary resources.

The last aspect to be examined regarding ABS in transboundary situations is that the benefits use in supporting the conservation of biodiversity and the sustainable use of its components globally. As mentioned above, the concepts of fairness and equity involve the idea of justice. Likewise, it was pointed out that social interactions are a key factor in conservation outcomes. On this basis, states and ILCs could find it unfair and inequitable that the benefits arising from the utilisation of their GR and TK are used for global biodiversity conservation instead of being used to help them to meet their needs. This is the biggest weakness of the

[96] ibid 2.
[97] ibid 3-4.
[98] John Rawls, A Theory of Justice (Revised edn, Harvard University Press 1999). Cited in: Campbell and Hanich (n 87) 4.
[99] Morton Deutsch, 'Equity, Equality, and Need: What Determines Which Value Will Be Used as the Basis of Distributive Justice?' (1975) 31 Journal of Social Issues 137. Cited in: Campbell and Hanich (n 87) 4.
[100] Dinah Shelton, 'Equity' in Daniel Bodansky, Jutta Brunnée and Ellen Hey (eds), The Oxford Handbook of International Environmental Law (OUP 2007). Cited in: Campbell and Hanich (n 87) 4.
[101] ibid 6.

proposed mechanism because, as set out earlier, providers are not likely to be motivated to share their resources. For this reason, a GMBSM should consider a system in which countries and ILCs are the first beneficiaries of the benefits arising from the use of their GR and TK, otherwise, it is highly probable that such a mechanism will never be implemented.

Against this background, it seems that the contribution of countries and ILCs to the conservation of biodiversity should be included in the distribution of benefits. As explained earlier in this section, a fair and equitable distribution of benefits derived from the utilisation of GR and TK could be achieved if, in addition to the economic value of these resources, considerations about conceptual framing elements of responsibility and rights are taken into account.

6.2.6 Need for Legal Provisions and Standards to enable fair and equitable sharing of benefits

MATs are the instrument whereby the 'fair and equitable' sharing of benefits should be achieved. Because of that, for Tvedt and Young, the Parties to the CBD and the NP are in need of 'legal provisions and standards to enable all users (and providers/sources) to know what is required – and especially to know when the arrangements they make will meet the required standard of "fair and equitable" sharing.'[102] In case of dispute, this guidance is required for courts, arbitrators, officials, and others seeking to determine whether the benefits agreed in MATs are fair and equitable.

In order to fulfil this end, they propose that national laws provide for:[103]

i. Clarification of what could be understood as 'fair sharing' i.e., provide some standards and other bases for determining the value of the resource and the manner in which it should (or can) be paid, including differences between monetary and non-monetary benefits;
ii. Equity, i.e., reflection on the contribution and needs of source countries, along with contributions to the local economy, research directed towards priority needs, food and livelihood, security benefits, social recognition, among others; and
iii. Practical application of these concepts.

6.3 Benefits

The CBD includes some examples of Benefits in Articles 15.6, 15.7, 16.3, 16.4, 19.1, and 19.2. However, the first instrument to specify the type of activities that could be considered as

[102] (n 12) p. 83
[103] ibid, pp. 83-87

benefits was the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation (the Bonn Guidelines).

This instrument was created with the aim of guiding the parties to the CBD in the development of their national laws concerning ABS. Its Appendix II condenses some examples of monetary and non-monetary benefits that users can share with providers to fulfil their ABS obligations.

For its part, and with only a few differences, the Annex of the NP reproduces the list of benefits enclosed in the Bonn Guidelines. As their name suggests, the examples of monetary benefits consist of payment methods, including fees, payment of royalties, salaries, or joint ownership of IPRs. Similarly, the list of non-monetary benefits describes activities such as the sharing of research and development results, participation in product development and the admittance to *ex-situ* facilities of GR and databases.

A comparison between the benefits described in the CBD, the Bonn Guidelines, and the Protocol is presented in Table 8.

The Table shows that the disparity between the texts of the Bonn Guidelines and the NP is in the use of the words 'provider country' and 'country providing genetic resources.' As explained in Sections 6.1.1 and 6.1.2 of the next section, there is no difference between the expressions 'provider country' and 'the Party providing the resources'. However, the exclusion of TK from the Protocol's list of benefits does not seem to be justified.

The Bonn Guidelines omission is understandable because the CBD does not explicitly include TK within the scope of ABS, and the Bonn Guidelines were written in 2002 before the Protocol was enacted. Nonetheless, this omission does not mean that ILCs are not entitled to receive the monetary and non-monetary benefits described therein.

For that reason, it can be argued that the conceptualisation of the term 'benefits' has no negative effect on ABS. The valuation of GR and TK as merely raw materials, and the culture of utilisation-without-compensation, emerged as a consequence of the fact that for a long time users did not compensate providers for the utilisation of their resources. This seems to be a real factor affecting negotiations about the benefits to distribute.

Table 8. Comparison of the Benefits as described in the CBD, the Bonn Guidelines and the Nagoya Protocol

<table>
<tr><td colspan="2">CBD, Article 15.6: Participation of providing countries in scientific research based on their GR.</td></tr>
<tr><td>CBD, Article 15.7</td><td>Nagoya Protocol, Article 5</td></tr>
<tr><td>1. The results of research and development;
2. Benefits arising from commercial utilisation; and
3. Benefits arising from other utilisation.</td><td>1. GR:
a. Benefits arising from the utilisation of GR;
b. Subsequent applications; and
c. Commercialisation.
2. The benefits arising from the utilisation of GR held by traditional communities should be shared with the communities concerned; and
3. Benefits arising from the utilisation of TK associated with GR should be shared with the traditional communities holding such knowledge.</td></tr>
<tr><td colspan="2">CBD, Article 16.3: Transfer to providing countries of technology which makes use of GR.</td></tr>
<tr><td colspan="2">CBD, Article 16.4: Private companies from user countries, should facilitate access to, join development and transfer of technology mentioned in Article 16.3 CBD, for the benefit of governmental and the private sector of developing countries.</td></tr>
<tr><td colspan="2">CBD, Article 19.1: Participation of providing countries in biotechnological research based on their GR.</td></tr>
<tr><td colspan="2">CBD, Article 19.2: Promote and advance priority access of providing countries to the results and benefits arising out from biotechnologies based upon the GR provided.</td></tr>
<tr><td>Bonn Guidelines</td><td>Nagoya Protocol</td></tr>
<tr><td>2. Non-monetary benefits may include, but not be limited to:
(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the provider country;</td><td>2. Non-monetary benefits may include, but not be limited to:
(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;</td></tr>
<tr><td>2. (g) Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;</td><td>2. (g) Strengthening capacities for technology transfer;</td></tr>
<tr><td>2. (j) Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;</td><td>2. (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;</td></tr>
<tr><td>2. (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;</td><td>2. (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;</td></tr>
</table>

This table has been made by the author from the texts of the CBD, the NP, and the Bonn Guidelines, as indicated in the table

7. The Parties of ABS

The parties of ABS are providers and users. Providers are the countries of origin of GR, TK and other parties to the CBD, provided that such resources were acquired according to the CBD or were accessed before the Convention came into force. The user is the party seeking access to the resources. However, there is no clear line between providers and users. Sometimes providers and users are the same entity

Despite complexities in accessing GR and TK, the relationship between providers and users of such resources, as recorded in the CBD, have been reduced to the mutual satisfaction of their needs. In other words, it is believed that providers have something users want, and that those users have something providers want.

Following this logic, ABS was built upon the idea that providers host a significant amount of natural resources and TK, but have fewer or less advanced technologies. Similarly, it was thought that users have a smaller number and/or variety of natural resources, but are industrialised countries with better opportunities to have, use, and improve the technologies needed to transform natural resources and TK into useful products.

For these reasons, the relationships between providers and users of GR and TK consist of the obligation for providers to facilitate access to their resources, and the consequent users' commitment to share the benefits obtained from the utilisation of such resources, including by appropriate transfer of relevant technologies. In this way, providers would be able to access the technologies they do not have, and obtain some profit from the use of their resources, while users could facilitate access to the resources they want.

The following sections explains the meaning of providers and users. ILCs are included because they could be providers of GR and TK when such a right is recognised through the provider countries' ABS laws.

7.1 The provider of GR

7.1.1 Country of Origin of GR

To establish the person entitled to provide GR, it is necessary to review some of the concepts in the CBD. As the ABS is a right, born in connection with the exercise of sovereign rights, the notion of provider has been built over that right. In fact, the ABS transactions designed in the CBD are meant to be developed by their Parties, in other words, by countries. One country is the provider and the other is the user. The first relevant concept is country of origin of GR.

The country of origin is described in Article 2 CBD as 'the country which possesses those resources in *in-situ* conditions.' The mention of the conditions in which the resources can be found directly relates to the sovereign rights of the countries over the resources found within their frontiers, and begs the question as to the legal status of the resources in *ex-situ*

conditions. The response to this question leads straight into the concept of providing country, which is explained in the following section.

7.1.2 County providing GR

In this respect, the CBD indicates, in Article 2, that the country providing GR is the one 'supplying GR collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.' From these concepts, some preliminary conclusions can be drafted: (i) the provider is a country, not a natural or a legal person (i.e., not a researcher or an *ex-situ* centre); (ii) the resources given can be found in *in-situ* and *ex-situ* conditions; and (iii) the providing country is not necessarily, at the same time, the country of origin of the resources. However, as already stated, when GR is accessed through an *ex-situ* centre, it is required that the resources have been legally acquired, i.e., in accordance with the CBD or before its entry into force. Therefore, pursuant to Article 2 CBD, the 'provider country' is the one supplying GR collected from *in-situ* sources (including populations of wild or domesticated species) or taken from *ex-situ* sources (which may or may not have originated in that country) (Article 15.3, CBD). As mentioned above, access *ex-situ* is one of the biggest voids left in the CBD and has a negative impact on ABS.

7.2 The provider of TK: indigenous and local communities (ILCs)

The responsible people of TK creation are described in Article 8j CBD as human groups 'embodying traditional lifestyles'. As mentioned in Section 3.3.3 of this chapter, this is the aspect which distinguishes them from other human groups developing knowledge about the use and management of biodiversity, such as scientists over many hundreds of years of study.

While this is certainly an important characteristic of these communities, this concept does not offer enough clarity concerning the kind of communities who could claim a distribution of benefits arising out of the utilisation of their TK. In this context, the question of who could be an ILC results in the possibility of 'someone' being identified as the person who may claim and exercise certain rights.

Different concepts about which human group falls to be considered as having a traditional lifestyle have been incorporated into local and regional laws in various parts of the world. A brief comparative analysis of accessible legislation permits the identification of more elements than the one provided in the CBD. From this, and according to the laws reviewed in Chapter 2, it is noticeable that ILCs are:

i. Always a collective group 'human group' (Brazil);[104] 'human population' (OAU)[105];
ii. With specific cultural characteristics that make them clearly different from the rest of society (Brazil,[106] Peru[107]);
iii. Collectively regarded as the creators of TK (Ethiopia,[108] India,[109] Panama,[110] and ARIPO[111]); and,
iv. Therefore, collective owners of their TK (Bhutan,[112] India,[113] and ARIPO[114]). In these laws, the ownership characteristic is sometimes accompanied by the description of the kind of goods that comprise TK (Panama[115] and ARIPO[116]).

For a better understanding of the differences between indigenous and local communities and their common elements, each concept is explained below.

7.2.1 Indigenous peoples

Indigenous peoples are described, for example, as 'any community of people' (South Africa),[117] as 'rural and native communities' (Peru),[118] and as 'descendant from indigenous peoples' (ILO Convention 169).[119] These may all be general references, as indigenous peoples are easily identified by their legal status according to rules made, for example, by the governments of the countries in which they live.

They have also been illustrated as 'those which, having a historical continuity with pre-invasion and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing in those countries, or parts of them. They form at present non-dominant sectors of society and are determined to preserve,

[104] (n 38) Article 2.
[105] African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, 2000, Organisation of Africa Unity (OAU), Algeria, Article 1
[106] ibidem (n 100)
[107] (n 39) Article 2.
[108] Ethiopia, Access to Genetic Resources and Community Knowledge, and Community Rights Council of Ministers Regulation No. 169/2009, Part 1 Articles 2 and 2.6, Part 3 Article 2.1
[109] India, The Biological Diversity Act, 2002, Article 2a 'benefit claimers'
[110] (n 47) Article 1.
[111] African Regional Intellectual Property Organisation (ARIPO), Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, Adopted by the Diplomatic Conference of ARIPO at Swakopmund (Namibia) on August 9, 2010, Part II, Sections 4(iii) and 5
[112] (n 43) Article 6p
[113] ibid (n 109)
[114] (n 111) Part I, Section 2.1, Part II, Section 5
[115] (n 47) Article 6.
[116] (n 111) Part II, Section 4
[117] Republic of South Africa, National Environmental Management: Biodiversity Act, 2004, Article 1.
[118] (n 39) Article 2.
[119] International Labour Organisation (ILO), Convention No. 169 of 1989, Convention concerning Indigenous and Tribal Peoples in Independent Countries, Article 1.1b

develop and transmit to future generations their ancestral territories, and their ethnic identities, as the basis of their continued existence as peoples, in accordance with their own cultural pattern, social institutions and legal systems.'[120]

Similarly, it has been argued that indigenous peoples usually 'include cultural groups and their descendants who have a historical continuity or association with a given region, or parts of a region, and who currently inhabit or have formerly inhabited the region either before its subsequent colonization or annexation, or alongside other cultural groups during the formation of a nation-state, or independently or largely isolated from the influence of the claimed governance by a nation-state, and who furthermore have maintained, at least in part, their distinct linguistic, cultural and social / organizational characteristics, and in doing so remain differentiated in some degree from the surrounding populations and dominant culture of the nation-state. Also include people who are self-identified as indigenous, and those recognized as such by other groups.'[121]

7.2.2 Local communities

In contrast, the identification of local communities seems to be more difficult. Primarily it can be seen that local communities are non-indigenous descendants, as occurs with African and Asian traditional communities. This element has been included in the law of countries such as Brazil,[122] Burundi,[123] South Africa,[124] and the ARIPO.[125] Furthermore, in countries with indigenous peoples, some communities of non-indigenous descendants with traditional lifestyles have also been considered as a part of ILCs, e.g., craftsmen and peasants. On this basis, craftsmen were included in Panamanian law for the protection of TK,[126] and the Colombian Multicultural Public Policy Proposal for the Protection of Knowledge Systems Associated with Biodiversity considers country folk, afro-descendants, and the 'rom' people (Romany people) as local communities.[127] It should be highlighted that Colombian recognition of its local communities was made on the basis of the traditional lifestyle of these people. This is the reason why it includes two non-American native groups: afro-descendants and rom. The first group arrived in America from Africa during the colonial period, and the second from

[120] WIPO (n 25) Annex 20.
[121] Charlotte Salpin, Arnold Kreilhuber and Elizabeth Mrema, *Glossary of Terms for Negotiators of Multilateral Environmental Agreements* (Bakary Kante ed, UNEP 2007), 49-50.
[122] (n 38) Article 2iv 'traditional community'
[123] (n 42) Article 2 'local communities'
[124] (n 117) Article 1.
[125] (n 111) Part II, Section 6.
[126] (n 47) 'Article 23: Small-scale non-indigenous craftspeople who earn their living producing, reproducing and selling replicas of Ngöbe and Buglé indigenous crafts and who reside in the districts of Tolé, Remedios, San Félix and San Lorenzo in the province of Chiriquí shall be exempt from the present Act. These small-scale nonindigenous craftspeople may manufacture and market these replicas, but they may not claim the collective rights of indigenous peoples recognized by this Act.'
[127] Marcela Jiménez Larrarte, *Propuesta de Política Pública Pluricultural para la Protección de los Sistemas de Conocimiento Asociado a la Biodiversidad en Colombia*, (Ministerio de Ambiente 2013), 14, 18-21.

Europe as a consequence of more recent migrations.

Local communities have also been understood as 'the human population in a distinct ecological area who depend directly on its biodiversity and ecosystem goods and services for all or part of their livelihood and who have developed or acquired traditional knowledge as a result of this dependence, including farmers, fisherfolk, pastoralists, forest dwellers, and others.'[128] These communities are also named 'tribal people' in ILO Convention169. According to this instrument, they are those 'whose social, cultural and economic conditions distinguish them from other sections of the national community, and whose status is regulated wholly or partially by their own customs or traditions or by special laws or regulation.'[129] For its part, the Inter-American Court of Human Rights (IACHR) acknowledges that tribal peoples are those 'not indigenous to the region, but that share similar characteristics with indigenous peoples, such as having social, cultural and economic traditions different from other sections of the national community, identifying themselves with their ancestral territories, and regulating themselves, at least partially, by their own norms, customs, and traditions.'[130] In addition, both the World Intellectual Property Organisation (WIPO)[131] and the FAO[132] have been using the terms 'local communities' and 'indigenous peoples' to identify the right holders of TK. In other words, within the international forums dealing with ABS, indigenous peoples and local communities are recognised as the beneficiaries of ABS and right holders of TK.

7.2.3 The common characteristics in the concepts of indigenous and local communities (ILCs)

Within the ABS context, the traditional lifestyle is what characterises a community as ILCs and, consequently, as having the right to grant PIC and benefit from the use of their TK. This element has been recognised as a distinct cultural way of being and understanding the world, which is adopted by a group of people, who identify themselves as a different group from the rest of the society in which they live, precisely for sharing their particular cultural lifestyle among all members of the group. In addition, the following characteristics are also found in the concepts of indigenous peoples and local communities previously presented:

i. Indigenous and local communities can be both descendant and non-descendant indigenous;
ii. They have a collective nature, expressed in, for example:

[128] CBD, Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity, 'Development of Elements of Sui Generis Systems for the Protection of Traditional Knowledge, Innovations and Practices' (2005) UNEP/CBD/WG8J/4/INF/18, 5.
[129] (n 119) Article 1.1a
[130] Case of the Saramaka People v. Suriname (n 58) para 79.
[131] WIPO, Secretariat of the World Intellectual Property Organisation, 'The Protection of Traditional Knowledge: Draft Articles' (2016) WIPO/GRTKF/IC/31/4, Annex 8, Article 2.
[132] FAO, International Treaty on Plant Genetic Resources for Food and Agriculture (adopted 03 November 2001, entered into force 29 June 2004) 2400 UNTS 303 (ITPGRFA), Article 9.

a. Always being a human group that is markedly different from the rest of society, in aspects such as culture, economy, and social or political institutions;
b. Their TK is collectively created, held and owned; and
c. Their rights have a collective nature resulting, for example, in the collective exercise of some human rights (e.g. property rights over the land and the resources located therein);

iii. They live in a close relationship with natural resources, and sometimes have historically been attached to geographically-distinct habitats or ancestral territories;
iv. Their status is regulated wholly or partially by their own norms, customs, or traditions, or by special state laws or regulations; and
v. They self-identify as a different part of society; as a 'traditional community'.

As can be seen in the concepts set out in this section and Section 3.3.3, ILCs have been identified in different national laws and international instruments as the developers, keepers, and rightsholders of TK. The existence of national laws allocating rights to ILCs over their TK in ABS transactions seems to indicate that the CBD does not prevent such a recognition or the protection of ILCs' rights through the development of national laws.

Nevertheless, it should be remembered that the national approach to compliance with the ABS obligations is a factor that significantly affects the possibility of providers achieving a distribution of benefits when their resources are used. In this regard, the limitation placed by the CBD on the distribution of benefits from TK utilisation does not result from the narrow scope of a concept, such as in the case of GR, but from the exclusion of ILCs and TK from the Article ruling ABS. This means that the recognition of ILCs as providers of TK is not an obligation for the Parties to the CBD, but a voluntary acknowledgement that these Parties could make via national laws. This can be seen as a factor limiting ABS transaction on TK.

7.3 Users of GR and TK

Users of GR and TK are responsible for sharing the benefits derived from their utilisation with the providers. They seek access for different reasons, including basic research, applied research, or the development of marketable products. This is why users can comprise research institutes, universities, industry researchers, *ex-situ* centres. and private companies. They operate in a wide range of sectors, namely pharmaceutical, biotechnology, the cosmetics industry, seed and crop protection, horticulture, cosmetic and personal care, fragrance and flavour, botanicals, and food and beverage industries.[133]

[133] Sarah Laird and Rachel Wynberg, *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors*, (Secretariat of the Convention on Biological Diversity, CBD Technical Series No. 38, 2008), 8.

8. Conclusion

The contents of the CBD and the NP set out the scope of ABS and specify the parties' obligations for the access and utilisation of GR and TK. Therein lies the importance of studying these legal texts. Despite their limitations, there is also the impossibility for countries to achieve better agreement. This is, perhaps, the fundamental obstacle for the establishment of a more functional ABS system, or at least one that is different from what now exists. Given that reality, the choices are either to do nothing or to examine these laws to understand their meaning and identify those aspects that may require revision. Taking this latter choice means being prepared for when countries feel ready to enter into new negotiations. Having chosen the second option for this study, this chapter has analysed the contents of the CBD and NP and identified a number of concerns.

Notably, a number of concepts within the CBD and NP require attention due to their inaccuracy or even omission; for instance, in the case of the term 'access', which is not defined in the CBD or NP. Above all, the following aspects must be clarified towards better functionality of ABS: (i) the meaning of GR and TK; (ii) the expansion of their scope to make them operational and in line with new technologies; (iii) the inclusion of new aspects such as derivatives and information; (iv) the identification of *ex-situ* centres' role, obligations and rights; (v) the actions that triggers ABS obligations; and (vi) the way the concept of the 'public domain' should be applied in ABS contexts.

In addition, the analysis of the legal texts reveals some limitations to the exercise of ABS. First, in both the CBD and NP it seems to be clear that GR accessed before the CBD fall outside the ABS scope. Second, that access to GR and TK should be facilitated. Third, that PIC is a prerequisite for access. Fourth, that providers of GR and TK have the right to benefit from the use of their resources. Fifth, that those benefits could be monetary and/or non-monetary. Sixth, that human GR are outside the ABS scope. Additionally, because principles and concepts of international environmental law can be found in the CBD, the concepts of 'fair and equitable' could be interpreted using other international instruments and international jurisprudence from this legal field.

The aspects mentioned above seem to indicate that the contents of the CBD and NP are a factor contributing to the limited efficiency of the ABS system. Together, they underpin the different interpretations and implementation of the CBD and NP found in national laws, which in turn can be considered the main source for legal complications when compliance at the international level is sought.

Under the current state of affairs, it would be useful for countries to develop and implement their national ABS laws by integrating the existing usual international practices on GR and TK utilisation. It is also recommended that, while implementing, the legal instruments should aim to be as clear as possible in the delimitation and establishment of the ABS scope, obligations, processes and requirements.

CHAPTER 5. The international system of ABS: the ABS Systems of the CBD, FAO and WHO

1. Introduction

Chapters 3 and 4 concluded that the ABS system of the CBD does not work properly as a consequence of failures in its design and legal vacuums in the content and scope of the elements it comprises. However, it can be argued that these are not the only causes of the failure of ABS. As the CBD is not the only international instrument regulating the distribution of benefits arising out of the utilisation of GR and TK, it is frequently claimed that such a failure occurs because the laws and rules of the different instruments comprising the international ABS system overlap to such a degree that they make the distribution of benefits difficult to achieve.[1] In response to these claims, this chapter argues that the rules of the international ABS system do not contradict or overlap, but are instead mutually supportive, as they were created for that purpose. To support this claim, the chapter describes the FAO and WHO ABS systems, showing the ways in which they interrelated with the CBD.

The chapter also concludes by suggesting that access to GR that should be occurring through the CBD is instead probably being conducted through the FAO and WHO ABS systems. As the CBD does not regulate access *ex-situ*, this might be one of the principal problems in achieving the distribution of benefits.

2. The FAO ABS system

2.1 Background: its negotiation process

As with the CBD, the FAO ABS system is the result of a long process of negotiation which was strongly influenced by discussions taking place in other trading venues. The international negotiations concerning the use of biodiversity started within the World Trade Organisation (WTO) in connection with agricultural trade. The need for a change in the protectionist and distorting policies in agriculture was first raised at the twelfth session of the contracting parties in 1957. Gottfried Haberler was appointed as chair to examine international trade trends, assess their future and prepare a report with suggestions for furthering the objectives of the

[1] See for example: Ulrich Brand and others, *Conflicts in Environmental Regulation and the Internationalisation of the State: Contested terrains* (Routledge/Ripe, Studies in Global Political Economy, 2008), CBD, Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing 'Study on the Relationship Between an International Regime on Access and Benefit-Sharing and Other International Instruments and Forums that Govern the Use of Genetic Resources' (2009) UNEP/CBD/WG-ABS/7/INF/3/Part.1, 125-127; 3.2.19, 3.2.20; Mathias Koenig-Archibugi and Michael Zürn (eds), *New Models of Governance in the Global System: Exploring publicness, delegation and inclusiveness* (Palgrave MacMillan, 2006), 66-73.

multilateral trading system. However, it was not until the Uruguay Round in 1994 that the Agreement on Agriculture was achieved as a concrete result of these negotiations.[2]

In this context, Article 20 of the WTO Agreement on Agriculture mandates negotiations for continuing the agricultural trade process.[3] However, its tariff system or green box has been criticised for allegedly promoting unfair competition in developing countries.[4] This is because, under such a system, developed countries can reduce tariffs on small farmers while simultaneously granting national subsidies for agriculture.[5]

After concluding the WTO Agreement on Agriculture, negotiations concerning the use of GR for agriculture continued within the FAO. The key stages in these negotiations are as follows:

i. The adoption of the International Undertaking on Plant Genetic Resources in 1983 (Resolution 8/83);
ii. The development of the concept of farmers' rights in 1986;
iii. The inclusion of the concept of farmers' rights in a binding instrument in 1989 (Resolution 5/89);
iv. The creation of the International Code of Conduct for Plant Germplasm Collection and Transfer in 1993 (Resolution 8/93);
v. The adoption of the International Treaty of Plant Genetic Resources for Food and Agriculture (ITPGRFA) in 2001, which incorporates the FAO ABS system (Resolution 3/2001); and
vi. The creation of a Standard Material Transfer Agreement (SMTA) to serve as a guide for research centres and *ex-situ* collections in 2006 (Resolution 1/2006).

These negotiations also reveal changes in the notion of property rights over GR. Its implications for the distribution of benefits are presented in the next section.

[2] Néstor Stancanelli, 'The Historical Context of the Green Box' in Ricardo Meléndez Ortiz, Christophe Bellmann and Jonathan Hepburn (eds), *Agricultural Subsidies in the WTO Green Box. Ensuring Coherence with Sustainable Development Goals* (CUP 2009), 23.

[3] WTO, Agreement on Agriculture (15 April 1994) LT/UR/A-1A/2, Article 20.

[4] The WTO Agreement on Agriculture includes a classification of subsidies for agriculture into 'boxes'. The inclusion of products in such boxes depends on their effects on production and trade. This way, amber serves to identify domestic support measures considered to distort production and trade; blue (amber box with conditions), any support that additionally requires farmers to limit production; and green (defined in Annex 2 of the Agreement), subsidies causing not more than minimal distortion of trade production, they have to be government-funded and must not involve price support.
More information available on: WTO, 'Domestic support in agriculture: The boxes' <https://www.wto.org/english/tratop_e/agric_e/agboxes_e.htm> accessed 10 October 2016.

[5] Timothy Josling, *Rethinking the Rules for Agricultural Subsidies* (E15Initiative, International Centre for Trade and Sustainable Development (ICTSD) and World Economic Forum 2015), 2,3.

2.2 Changes in the concept of property rights over plant GR for food and agriculture

While agriculture was discussed in terms of agricultural trade at the WTO, within the FAO the discussion included the nature of the rights that would allow the use of plant GR for food and agriculture. This discussion had two clear phases: one in which plant GR for food and agriculture were considered to be freely available for use, and another in which these resources were deemed to be subject to state sovereignty. What this draws attention to is the fact that these opposing ways of conceiving property rights over plant GR for food and agriculture were developed from the idea that these resources are humankind's heritage.

In the first phase, before the Uruguay Round began, the International Undertaking on Plant Genetic Resources (the International Undertaking) was adopted through Resolution 8/83. The language of the Resolution reflects the concept of property rights over nature in existence at that time. The International Undertaking stated that 'plant genetic resources are a heritage to be preserved and freely available for use for the benefit of present and future generations.'[6] What the International Undertaking reflects is the consideration of such resources as part of the 'common heritage of mankind' that allowed their free access and utilisation.

In this specific context, it was considered that plant GR for food and agriculture should remain free to allow the development of scientific research, plant breeding or GR conservation without the possibility of national sovereign rights being claimed over them.[7] As pointed out by Philippe Cullet, this was the guidance concerning the management of the Consultative Group on International Agricultural Research (CGIAR),[8] which worked on the basis of sharing resources and information located in *ex-situ* collections.[9]

Moreover, because the language used in the International Undertaking does not impose limitations on the concept of plant GR for food and agriculture, it was also understood that (i) traditional cultivars (in current use and newly-developed varieties), (ii) obsolete cultivars, (iii) primitive cultivars, (iv) wild and weed species, (v) special genetic stocks (including elite and current breeders' lines and mutants),[10] and the varieties developed by scientists in laboratories were covered by FAO Resolution 8/83.[11] Apparently, the free availability of plant GR for food and agriculture improved in laboratories was an obstacle to the acceptance of the International Undertaking, especially by developed countries with interests in the trade of

[6] FAO, Res 8/83 'International Undertaking on Plant Genetic Resources' (adopted 23 November 1983).
[7] ibid. Annex, Art. 5
[8] The CGIAR is a global agricultural research body devoted to 'advance agri-food science and innovation to enable poor people, especially poor women, to increase agricultural productivity and resilience, share in economic growth, feed themselves and their families better, and conserve natural resources in the face of climate change and other threats.'
More information available in:
CGIAR, 'CGIAR A Global Agricultural Research Partnership' <http://www.cgiar.org/> accessed 11 October 2016.
[9] Philippe Cullet, 'The International Treaty on Plant Genetic Resources for Food and Agriculture' (2003) IELRC Briefing Paper 2003-2, 2-3.
[10] FAO, International Undertaking on Plant Genetic Resources (n 6) Annex, Art. 2.1a
[11] Cullet (n 9) 1.

these products. Agreement on this topic was only achieved in 2001 following a change in the concept of property rights over plant GR for food and agriculture.

The international negotiations within the FAO led to Resolutions 4/89 and 5/89. These respectively observe that plant breeders' rights, as contemplated in the International Convention for the Protection of New Varieties of Plants (UPOV),[12] were not inconsistent with the International Undertaking and introduce the concept of farmers' rights in recognition of the contributions made by farmers in conserving, improving and making available GR for food and agriculture.[13]

The importance of the notion of farmer's rights is that it introduces for first time the right for farmers 'to participate fully in the benefits derived, at present and in the future, from the improved use of plant genetic resources, through plant breeding and other scientific methods.' Thus, farmers' rights can be regarded as the most important precedent in the acknowledgement of the right of ILCs to be compensated for the use of their TK.

By the time these Resolutions were devised, the United Nations Environmental Programme (UNEP) had established an Ad Hoc Working Group of Technical and Legal Experts to create a text for an international convention on biological diversity. The working group then became the Intergovernmental Negotiating Committee that elaborated the later drafts of the CBD. During these discussions, the United States of America (USA), supported by Japan, expressed an interest in access to biodiversity, laboratory production of genetically modified organisms (GMOs), and their protection through intellectual property rights, while opposing PIC and ABS over GMOs and biotechnology products.[14] In the opinion of Cullet, this position caused a strong reaction from developing countries,[15] and is perhaps the factor triggering the

[12] According to its Articles 1 and 2, the International Convention for the Protection of New Varieties of Plants of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991 (UPOV) aims 'to recognise and to ensure to the breeder of a new plant variety or to his successor in title' a right over such new plant variety, which may be granted 'either of a special title of protection or of a patent.'
More information available in: UPOV, 'International Union for the Protection of New Varieties of Plants' (2011) <http://www.upov.int/upovlex/en/upov_convention.html> accessed 10 October 2016.

[13] FAO, Resolution 5/89 'Framers' Rights' (adopted 29 November 1989). 'Framers' Rights mean rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the International Community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions, as well as the attainment of the overall purposes of the International Undertaking) in order to:
a) ensure that the need for conservation is globally recognized and that sufficient funds for these purposes will be available;
b) assist farmers and farming communities, in all regions of the world, but especially in the areas of origin/diversity of plant genetic resources, in the protection and conservation of their plant genetic resources, and of the natural biosphere;
c) allow farmers, their communities, and countries in all regions, to participate fully in the benefits derived, at present and in the future, from the improved use of plant genetic resources, through plant breeding and other scientific methods.'

[14] Laurence Boisson de Chazournes, 'Convention on Biological Diversity and Its Protocol on Biosafety' (United Nations Audiovisual Library of International Law 2009) <http://legal.un.org/avl/pdf/ha/cpbcbd/cpbcbd_e.pdf> accessed 10 October 2016, p. 3

[15] Cullet (n 9) 2.

change in the concept of property rights over GR which occurred within the FAO and was subsequently implemented in the CBD.

In the middle of discussions within the CBD, through Resolution 3/91, the FAO recognised the sovereign rights of countries over their plant GR for food and agriculture in these terms: 'The Conference, Recognising that: the concept of mankind's heritage, as applied in the International Undertaking on Plant Genetic Resources, is subject to the sovereignty of the states over their plant genetic resources, (…) conditions of access to plant genetic resources need further clarification; (…) Endorses the following points: 1. That nations have sovereign rights over their plant genetic resources;'

A comparison of the texts of FAO Resolutions 8/83 and 3/91, contained in Table 9, shows how the concept of mankind's heritage has been used to develop these different notions about property rights over GR.

Table 9. Notions of Property over GR built on the basis of the concept of Mankind's Heritage

Resolution 8/83	Resolution 3/91
Plant genetic resources are a heritage to be preserved, and to be freely available for use, for the benefit of present and future generations.	The concept of mankind's heritage, as applied in the International Undertaking on Plant Genetic Resources, is subject to the sovereignty of the States over their plant genetic resources. Nations have sovereign rights over their plant genetic resources.

This table has been made by the author from the text of Resolutions 8/83 and 3/91 of FAO, as indicated in the table

In the first phase, this concept supported the idea that GR are free to use, while subsequently noting that they are the objects of states' sovereign rights. This change in the conception of property rights over plant GR for food and agriculture within the FAO constitutes the direct precedent for the recognition of sovereign rights of states over their GR in the CBD. In turn, this is the pillar that provides legal support for ABS.

2.3 Harmonising the FAO and the CBD: the 2001 International Treaty of Plant Genetic Resources for Food and Agriculture

The year after the CBD was signed, through Resolution 7/93, the FAO Conference requested further revision of the International Undertaking and its harmonisation with the CBD. It also asked for ABS for plant GR for food and agriculture through *ex-situ* collections to be considered, as this issue had not been addressed by the Convention.[16] This last mandate

[16] FAO, Resolution 7/93 'Revision of the International Undertaking on Plant Genetic Resources' (adopted 22 November 1993).
'1. Requests the Director-General to provide a forum for negotiations among governments:

was made in recognition that the Nairobi Final Act of the CBD proposes that access to GR *ex-situ* collected before the CBD is an issue that should be resolved using the FAO system.[17]

For this purpose, the negotiations began at the First Extraordinary Session of the Commission on Plant Genetic Resources in November 1994 and ended with the adoption in 2001 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). This instrument recognises the sovereign rights of states over their plant GR for food and agriculture[18] and aims to achieve, 'in harmony with the CBD,' the fair and equitable sharing of the benefits arising out of their use,[19] including the protection of TK relevant to plant GR for food and agriculture, the right for ILCs to participate in the sharing of benefits, and decision-making on matters related to the preservation of plant GR for food and agriculture.[20] In addition, Articles 10-13 regulate the ABS system of FAO (multilateral system - MLS), which is explained in Section 2.6 of this chapter.

2.4 Access to GR through *ex-situ* collections and its relationship with the FAO ABS system

As mentioned earlier, since 1991 the FAO has recognised the sovereign rights of states over their plant GR (Resolution 3/91). However, it was not until 2001 that the ITPGRFA, containing an ABS system, was adopted. The consequence of the absence of a law regulating ABS was that the International Undertaking of 1983 was applied until 2001, although the common heritage principle espoused in that instrument had, by 1991, already been significantly modified by resolutions reasserting the sovereign rights of states over their GR and clarifying that 'free' access to such resources did not necessarily mean free of charge.

The relationship between the FAO and the CBD was also unclear. For this reason, GR located in *ex-situ* collections were freely accessed, used, and shared without ABS obligations until 2001. This is the case, for example, for the resources found in the collections under the CGIAR management, which comprise 'the world's largest and most diverse crop and forage germplasm, indispensable to future food security.'[21] The CGIAR is a global partnership carrying out scientific research on food and agriculture through fifteen centres, which integrate the

(a) for the adaptation of the International Undertaking on Plant Genetic Resources, in harmony with the Convention on Biological Diversity,
(b) for consideration of the issue of access on mutually agreed terms to plant genetic resources, including ex situ collections not addressed by the Convention,'

[17] Nairobi Final Act of the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity (1992) 31 ILM 842. Resolution 3: The Interrelationship between the Convention on Biological Diversity and the Promotion of Sustainable Agriculture. The Conference,
'4. Further recognizes the need to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular: (a) Access to *ex-situ* collections not acquired in accordance with this Convention; and (b) The question of farmers' rights.'

[18] FAO, International Treaty on Plant Genetic Resources for Food and Agriculture (adopted 03 November 2001, entered into force 29 June 2004) 2400 UNTS 303 (ITPGRFA), Article 10.1

[19] ibid, Article 1

[20] ibid, Article 9.2

[21] CGIAR, 'About Us' <http://www.cgiar.org/about-us/> accessed 11 October 2016.

CGIAR Consortium of International Agricultural Research Centres.[22] These centres are spread around the world and conduct research in close collaboration 'with hundreds of partners' including national and regional research institutes, civil society organisations, academia, development organisations and the private sector.[23] In other words, it seems that the CGIAR is one of the biggest providers of GR in the world, and that its resources have been accessed globally by many and different users.

Given the volume of accesses to plant GR that may have occurred through the *ex-situ* collections belonging to the CGIAR, and its philosophy of free sharing of GR, some concerns are raised regarding the use of such resources. For example: is there any factual or legal guarantee that the GR accessed through the collections belonging to the CGIAR have been used respecting the sovereign rights of their countries of origin and only for the purpose defined under the International Undertaking mandate? Are there assurances that those resources have not been used for purposes other than food and agriculture, such as pharmacology and medicine? Not having clear answers to such questions creates doubts as to whether the research associated with these resources has been conducted with the exclusive purpose of benefitting humankind, or whether it has also been used to develop marketable products with the mere interest of profit. Such doubts are very difficult to resolve, as it is very difficult for the provider country to trace the further use of the resources once they have been accessed, unless this information is disclosed by the user.

Access to GR through CGIAR collections highlights two different problems regarding the application of the ABS rules of the CBD. First, for the period between when the CBD entered into force (29 December 1993) and the adoption of the ITPGRFA (3 November 2001), many GR were accessed without fulfilling the ABS obligations of the CBD. Second, tracking and monitoring the subsequent uses of such resources is an almost impossible task because, among other things, the sharing of samples and their information is a common practice in research.[24] It could be interpreted that this practice goes not only against the sovereign rights of states over their GR regarding their exclusive right to grant access, but also points to possible gaps in information about who received samples initially stored in a CGIAR collection. That is to say, after a GR is given to a user, it is almost impossible to find out who the subsequent users are and the uses of that sample unless this information is recorded by the parties involved in the resource-sharing chain.

[22] These centres are: Africa Rice Centre, Biodiversity International, International Center for Tropical Agriculture, Centre for International Forestry Research, International Maize and Wheat Improvement Centre, International Potato Centre, International Centre for Agricultural Research in the Dry Areas, International Crops Research Institute for the Semi-Arid Tropics, International Food Policy Research Institute, International Institute of Tropical Agriculture, International Livestock Research Institute, International Rice Research Institute, International Water Management Institute, World Agroforestry Centre, and WorldFish.
More information in: CGIAR, 'Our Research Centres' <http://www.cgiar.org/about-us/research-centers/> accessed 11 October 2016.

[23] CGIAR (n 21)

[24] Myrna Watanabe, 'The Nagoya Protocol on Access and Benefit Sharing. International Treaty Poses Challenges for Biological Collections' (2015) 65 BioScience 543, 548.

For these reasons, access to GR through *ex-situ* collections has been perceived as one of the largest obstacles to ABS implementation. In fact, this is a topic of such controversy that, despite it being mentioned during the negotiation of the NP, agreement could not be reached.

2.5 Limits to the use of GR located in *ex-situ* collections

The use of GR *ex-situ* (such as the CGIAR gene banks), for purposes other than food and agriculture led to accusations which link the access of these resources with biopiracy.[25] This is particularly so because, allegedly, some uses were not for plant breeding and scientific purposes, and their benefit was not enjoyed by humanity in the abstract, but instead to satisfy private interests. In other words, using GR *ex-situ* in a different way to how it was authorised in the International Undertaking of 1983 is considered as a form of biopiracy.[26]

A possible scenario has been raised in which private companies were accessing GR through *ex-situ* collections to develop marketable products without distributing the benefits to the providers of GR. It should be keep in mind that the agreements on ABS are typically made between the *ex-situ* collection supplying the GR and the user of the resource.[27] That is to say, that the distribution of benefits is happening between the user and the *ex-situ* centre, rather than between the user and the provider country. The accusation of biopiracy was therefore built on the possibility that providers of GR are not benefitting from the use of their resources. Additionally, some claims of several non-governmental organisations (NGOs) and indigenous organisations demonstrate concerns about the use of associated TK in the developing process of those marketable products and the absence of a distribution of benefits to ILCs. Despite the fact that these reclamations usually do not to point specifically to the development of products using materials accessed *ex-situ*, the validity of their concerns cannot be denied, especially when it is very difficult to know the origin of the resources used.[28]

The need to clarify the uses of GR *ex-situ* becomes evident, because their access outside the CBD was potentially affecting both countries of origin and ILCs' rights. The first step in the achievement of this task was the change in the perception that GR were goods of free access, and the specific reference of sovereign rights expressed in the right for states to determine the conditions for accessing GR. The second step was identifying which crops are vital for food and agriculture and which are not. The identification of these crops was made with the intention

[25] Biopiracy is understood as the access and utilisation of GR and TK without fulfilling the obligations of the CBD.
[26] International Undertaking on Plant Genetic Resources (n 6).
'Article 1. Objective: The objective of this Undertaking is to ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes. This Undertaking is based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction.'
[27] Kate Davis and others, 'An Access and Benefit-Sharing Awareness Survey for Botanic Gardens: Are they prepared for the Nagoya Protocol?' (2015) 98 South African Journal of Botany 148, 153-154.
[28] See for example, the analysis of the cases of the International Cooperative Biodiversity Group (ICBG) with the Chiapas Highland Maya (Mexico) and the Aguaruna people (Peru):
Ronald Nigh, 'Maya Medicine in the Biological Gaze. Bioprospecting Research as Herbal Fetshism' (2002) 43 Current Anthropology 451, 652; Shane Greene, 'Indigenous Peoples Incorporated? Culture as Politics, Culture as Property in Pharmaceutical Bioprospecting' (2004) 45 Current Anthropology, 211.

of allowing their free use for food and agriculture. These were recorded in Annex I of the ITPGRFA.

2.6 The Multilateral System (MLS): the FAO ABS system

Paraphrasing the objectives of the CBD, the ITPGRFA aims are:

i. The conservation and sustainable use of plant GR for food and agriculture; and
ii. The fair and equitable sharing of the benefits arising out of their use.[29]

Notably the ITPGRFA aims to provide 'sustainable agriculture and food security', which have to be achieved 'by close linking' of the ITPGRFA with the CBD.[30] In this regard, the content of this treaty indicates that ABS under FAO rules should not oppose or contradict the ABS system of the CBD.

2.6.1 Kinds of utilisation

Access to plant GR for food and agriculture is limited to the exclusive realisation of two activities: utilisation and conservation. However, not all kinds of utilisation or conservation are permitted. These activities can be conducted solely for the purposes of research, breeding, and training for food and agriculture. The use and conservation of these resources for different purposes such as 'chemical, pharmaceutical and/or other non-food/feed industrial uses' are also not covered under the ITPGRFA.[31]

This last aspect is of vast importance because makes it clear that the utilisation and conservation (the latter being understood as the preservation by the user of the samples received for their further use) are restricted to activities related to food and agriculture. Consequently, any activity other than those triggers the obligation to conduct an ABS process under the CBD.

2.6.2 Conditions for the utilisation of GR under the FAO ABS system

Under the FAO ABS system, states only have an obligation to provide facilitated access to their plant GR for food and agriculture for those parties who have also included their GR in the MLS.[32]

In addition, it has been specifically established that facilitated access:

[29] International Treaty on Plant Genetic Resources for Food and Agriculture (n 18), Article 1.1
[30] ibid, Article 1.2
[31] ibid, Article 12a
[32] ibid, Articles 11.4, 12.2

i. Shall be accorded expeditiously, without tracking individual accessions, and free of charge or with a charge that should not exceed the minimal cost involved;
ii. All non-confidential information shall be made available;
iii. Recipients shall not claim IPRs or other rights that limit facilitated access to plant GR for food and agriculture in the form received from the FAO ABS;
iv. Plant GR for food and agriculture under development shall be at the discretion of its developer during the period of development;
v. Access to plant GR for food and agriculture protected by IPRs or other property rights shall be consistent with international and national laws;
vi. Plant GR for food and agriculture accessed under the MLS shall continue to be made available to this system under the terms of the ITPGRFA; and
vii. Plant GR for food and agriculture found in *ex-situ* conditions will be provided according to national legislation or, in absence of these laws, in accordance with the standards set by the Governing Body of the ITPGRFA.

One important aspect of these rules is related to IPRs. As noted earlier, users of plant GR for food and agriculture covered by the ITPGRFA cannot claim IPRs over the materials in the form they were received. This is because under the IP law of some countries it is possible to obtain IPRs over separate components or genetic parts of such materials. This limitation seeks to ensure that these resources cannot be appropriated by anyone, including States and private entities. An explanation for this can be found in the first FAO Millennium Development Goal,[33] consisting of the eradication of extreme poverty and hunger by, among other things, improving agricultural productivity. In this sense, for the purpose of conducting research on food and agriculture to improve agricultural productivity that helps to reduce poverty and hunger, the MLS has been designed to allow free access to those GR considered as the most important crops for world food security. For this same reason, it is also required that such GR continue to be free for research, breeding, and agriculture.

Consequently, utilising these resources for the satisfaction of private interests or in fields other than food and agriculture runs contrary to the spirit of the ITPGRFA.

2.6.3 GR *ex-situ* under the MLS

Two criteria were used to define which plant GR are covered under the MLS: the resources considered as such and the authorised uses described in the section above. It was therefore established that these plant GR are:

i. A list of most of the crops needed for human nutrition (Annex I of the ITPGRFA),[34] including those:

[33] More information available in: FAO, 'Sustainable Development Goals' (2016) <http://www.fao.org/sustainable-development-goals/mdg/en/> accessed 14 October 2016.
[34] International Treaty on Plant Genetic Resources for Food and Agriculture (n 18), Article 11.1

a. Under the management and control of the Contracting Parties,
b. In the public domain,[35] and
c. In the *ex-situ* collections of the CGIAR;[36] and

ii. Crops not listed in Annex I but collected before the CBD came into force.[37]

On this basis, accessing GR *ex-situ* through the MLS has two conditions. First, it is crucial that the genetic material corresponds to one of those comprising the previous list, and, second, that the resource is used in a way that has been authorised. Otherwise, these GR are covered by the rules of the ABS system of the CBD, meaning that PIC, MAT and a distribution of benefits must be conducted with the provider of the resource. Second, access to GR not listed in Annex I is possible if collected before the CBD.

2.6.4 GR *ex-situ* under the ABS system of the CBD

As can be inferred from the previous section, the ABS rules of the CBD must be followed for accessing:

i. Plant GR not included in Annex I, even when they were intended to be used and/or conserved for research, breeding, and training for food and agriculture;
ii. Plant GR included in Annex I but used for purposes other than those previously described, such as chemical, pharmaceutical, or other industrial utilisation; and
iii. GR collected after the CBD came into force, but used for purposes other than those described in paragraph i above, such as chemical, pharmaceutical or other industrial utilisation.

2.7 The structural elements of the MLS

2.7.1 No Prior Informed Consent (PIC)

The ITPGRFA covers a particular plant GR. These resources must be exclusively used for research on food and agriculture because the utmost purpose of these research activities is to benefit society in the abstract by, for example, contributing to eradicate poverty and hunger. With this aim, it was agreed that access to such plant GR must remain free, so anyone could conduct research which, in the end, would benefit humanity. Consequently, no sovereign rights or any other kind of property rights can be claimed over these plant GR.

[35] ibid, Article 11.2
[36] ibid, Article 11.5
[37] Nairobi Final Act (n 17). Resolution 3: The Interrelationship between the Convention on Biological Diversity and the Promotion of Sustainable Agriculture. The Conference,
'4. Further recognizes the need to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular: (a) Access to *ex-situ* collections not acquired in accordance with this Convention; and (b) The question of farmers' rights.'

In this context, PIC does not make sense. In other words, because no one can have property rights over specific GR, there is no one with the right to authorise their access.

It is paradoxical, however, that no one can have property rights over these resources but that this limitation does not exist for the developments made using them. This system appears to create the conditions for freely conducting research over some GR whose results may be privately appropriated. In other words, under this system, providers cannot claim property rights over their GR but users can obtain property rights over the developments achieved using such resources.

Finally, it must be remembered that GR *ex-situ* are subject to the CBD when they are not listed in Annex I of the ITPGRFA and/or used for purposes other than food and agriculture. Consequently, for these cases the user must obtain PIC from the provider country before conducting access.

2.7.2 Standard Material Transfer Agreement (MTA)

Facilitated access to plant GR for food and agriculture shall be provided pursuant to a standard material transfer agreement (MTA). A MTA is an agreement between the *ex-situ* collection supplying the resource and the user, which must contain: (i) the purpose of access; (ii) the benefit-sharing provisions; and, (iii) an indication that the conditions of the MTA apply to subsequent transfers of the resource to another person or entity.[38]

Through Resolution 1/2006, the Governing Body of the Treaty adopted a model MTA, and nowadays several research centres are operating in accordance with that model.[39]

2.7.3 The 1993 International Code of Conduct for Plant Germplasm Collecting and Transfer

A component of the MLS is the International Code of Conduct for Plant Germplasm Collecting and Transfer, adopted in 1993 as a voluntary instrument that could be used by governments to develop national regulations or bilateral agreements on the collection of germplasm.[40]

As shown in Table 10, by means of its consideration of the conservation and continued availability of plant GR as a common concern of humankind, this Code of Conduct seems to evoke the idea of facilitated access in Article 15.2 CBD by stating that access to plant GR should not be unduly restricted (Article 3.2).

The use of concepts such as 'mankind's heritage' and 'common concern of humankind' as a basis for claiming that access to GR should be both free, facilitated and subjected to

[38] International Treaty on Plant Genetic Resources for Food and Agriculture (n 18), Article 12.4

[39] See for example: CropGenebank Knowledge Base, 'Collecting plant genetic diversity: Technical guidelines. 2011 update' <http://cropgenebank.sgrp.cgiar.org/index.php/procedures-mainmenu-242/collecting> accessed 12 October 2016

[40] FAO, Resolution 8/93 'International Code of Conduct for Plant Germplasm Collecting and Transfer' (adopted 22 November 1993), Article 3.6

sovereign rights perhaps also provides evidence of the tension between provider and user countries, and their particular interests about the free or regulated access to these resources.

Table 10. Changes in the notion of Property over GR under FAO

Resolution 8/83	Resolution 3/91	International code of conduct for plant germplasm collecting and transfer, 1993
Plant genetic resources are a heritage to be preserved, and to be freely available for use, for the benefit of present and future generations.	The concept of mankind's heritage, as applied in the International Undertaking on Plant Genetic Resources, is subject to the sovereignty of the States over their plant genetic resources. Nations have sovereign rights over their plant genetic resources.	The code recognizes that nations have sovereign rights over their plant genetic resources in their territories and it is based on the principle according to which the conservation and continued availability of plant genetic resources is a common concern of humankind. In executing these rights, access to plant genetic resources should not be unduly restricted.

This table has been made by the author from the text of the Resolutions 8/83 and 3/91 of FAO, and the International Code of Conduct for Plant Germplasm Collecting and Transfer, as indicated in the table

2.8 The ABS obligations

2.8.1 Facilitated access

In the same way as the CBD establishes its ABS system, the ITPGRFA starts by affirming the sovereign rights of states over their plant GR for food and agriculture, including the authority to determine their access through national laws.[41] Subsequently, it is affirmed that in the exercise of such sovereign rights, states agree to establish the MLS,[42] which includes in its objectives:

i. Facilitating access to plant GR food and agriculture (the GR concerning is explained in Section 2.6.3 of this chapter); and
ii. Sharing, in a fair and equitable way, the benefits arising out of the utilisation of these resources, on a complementary and mutually-reinforcing basis.

On this matter there is no difference between the MLS and the CBD. In both cases, access must be facilitated by the provider of the resource. This obligation is, however, determined by the utilisation of GR. In this way, under the MLS, the obligation to facilitate

[41] International Treaty on Plant Genetic Resources for Food and Agriculture (n18), Article 10.1
[42] ibid, Article 10.2

access to GR only exists for their use in food and agriculture while access within the CBD must be for environmentally-sound uses.[43]

This limitation on the providers' responsibility regarding facilitating access has two effects. Firstly, any other utilisation will not generate the obligation to facilitate access. Secondly, access to plant GR for food and agriculture through the MLS utilised for purposes other than food and agriculture generates the obligation for users to share the benefits with providers rather than have them shared through the FAO fund, as explained in the next section.

2.8.2 Benefits derived from the utilisation of GR

MLS is a multilateral mechanism that facilitates access and the distribution of benefits derived from the use of plant GR for food and agriculture. Under this logic, 'facilitated access' is itself the major benefit for users.[44]

The system operates on a complementary and mutually-reinforcing basis, meaning that: (i) no one can claim property or other rights over them;[45] (ii) GR accessed through this mechanism shall continue to be made available;[46] and, (iii) the benefits will form a trust fund[47] from which money should flow primarily, directly and indirectly, to farmers and ILCs in developing countries and economies in transition.[48]

The fund operates in a simple way. Those who access materials through the MLS have an obligation to disclose any new development. However, users also have the option of keeping those new developments to themselves. In doing so, they only have to reach an agreement to pay a percentage of any commercial benefits into the common fund.[49]

This way of distributing benefits is the opposite of that established in the CBD. As explained in Chapter 4, under the Convention, the benefits must be distributed to the provider countries. For this reason, a clear identification of the plant GR for food and agriculture accessed under the MLS is of great importance, since this determines whether the benefits are shared with the provider country or not.

Similar to the CBD system, the MLS includes some examples of benefits. For example: the exchange of information,[50] access to and transfer of technology, capacity-building,[51] and

[43] Convention on Biological Diversity (adopted 05 June 1992, entered into force 29 December 1993) 1760 UNTS 79 (CBD), Article 15.2

[44] International Treaty on Plant Genetic Resources for Food and Agriculture (n 18), Article 13.1

[45] ibid, Article 12.3d

[46] ibid, Article 12.3g

[47] ibid, Article 13d.ii, 19.3f

[48] ibid, Article 13d

[49] More information about this fund is available in the web site:
Benefit-sharing Fund <http://www.planttreaty.org/content/benefits-multilateral-system> accessed 2 April 2017.

[50] These can include catalogues and inventories of crop diversity and the results of research. With regard to the sharing of information, the ITPGRFA provides the Global Information System, which serve to provide relevant information about crops in the MLS.
This system is available on: <http://www.planttreaty.org/content/multilateral-system> accessed 2 April 2017

[51] Such capacity building can involve programmes for scientific and technical education and training, help with the build of research facilities in developed countries and the collaborative development of research between developed and developing countries.

the sharing of monetary and other benefits of commercialisation.[52] It is noticeable that the provisions concerning ABS lack specificity which, again, could be an indication of the difficulties in balancing the interest of providers and users of GR during the negotiations of the ITPGRFA, also causes practical difficulties for the distribution of benefits.

Moreover, it can be appreciated that the benefits contained in the ITPGRFA are similar but not identical to the benefits set out in the CBD. Unlike the CBD, the FAO includes capacity-building as part of the distribution of benefits, but only enshrines the distribution of benefits from commercial use of these resources. In contrast, the CBD establishes the distribution of benefits for any use of such resources, either commercial or non-commercial, for which the Bonn Guidelines include some examples of monetary and non-monetary benefits to be utilised by the stakeholders. Therefore, under the CBD, non-commercial uses can result in non-commercial benefits, while commercial uses can be compensated with commercial and non-commercial benefits. Table 11 includes a comparison of the benefits in both systems.

Table 11. Comparison of the Benefits established in the ABS systems of FAO and the CBD

FAO	CBD
1. Exchange of information; 2. Access to and transfer of technology; 3. Capacity-building; and 4. Sharing of monetary and other benefits of commercialisation.	1. The results of research and development; 2. Benefits arising from the commercial utilisation; and 3. Benefits arising from other utilisation.

This table has been made by the author from Article 13.2 of the ITPGRFA and Article 15.7 of the CBD

2.8.3 Benefits derived from the utilisation of TK

In the same way as in the CBD, TK is not included in the Article regulating benefit-sharing of the ITPGRFA.[53] It has been interpreted that the distribution of benefits derived from the use of TK evolved from the content of Article 9.2b of the ITPGRFA, which includes the recognition of the farmers' rights. In this regard, the International Treaty provides that:

> '9. Farmers' rights:
> 1. The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and

[52] International Treaty on Plant Genetic Resources for Food and Agriculture (n 18), Article 13.2
[53] ibid, Articles 3 and 10

development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

2. (…) In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:
b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture;'
(Emphasis added)

The link between the content of the ITPGRFA and the incorporation of TK within the scope of the ABS system in the CBD has been established in relation to the recognition of the contribution of ILCs to the conservation and development of biodiversity. Over time, it was recognized that TK plays a key role in the development of such conservation and development activities. This recognition was incorporated into Articles 8j of the CBD and Article 3 of the NP.

Perhaps because of this, in the ITPGRFA, farmers and ILCs do not directly benefit from the utilisation of plant GR for food and agriculture. This occurs instead through FAO financial assistance delivered to farmers and ILCs through the funding strategy for farming that is part of the MLS.[54]

Although the ITPGRFA is limited to recognising the enormous contribution of farmers and ILCs to food and agriculture preservation and production,[55] these communities have been able to benefit from the MLS by retrieving money for funding some of their projects. Thus, maybe, in the case of ILCs, it would be better for the CBD to establish a benefit-sharing system similar to the one implemented in the MLS.

2.9 The Parties of ABS

As with the ABS system of the CBD, the parties of the FAO system are the countries of origin, *ex-situ* conservation centres, farmers (including ILCs), and users. These concepts were addressed in more detail in Section 6 of the previous chapter.

[54] ibid, Article 13.3
[55] ibid, Article 9.1

2.10 The ABS Process

The first step of functionality for the ITPGRFA involves the inclusion of plant GR for food and agriculture and their related information[56] in the system.[57] It also incorporates (i) the plant GR for food and agriculture located in the *ex-situ* collections of the International Agricultural Research Centres (IARCs) of the CGIAR;[58] and, (ii) complementarily, all holders of plant GR for food and agriculture listed in Annex I are invited to add these resources to the system.[59]

The information about the resources that are part of this system, as well as the *ex-situ* collection in which they can be found, is available on the web.[60] Thus, in practice, this ABS system is a focal point containing information on plant GR stored in different *ex-situ* collections across the world, instead of being a single place where all those resources are preserved.

In this way, access to plant GR for food and agriculture is through the *ex-situ* conservation centres in the world. These centres can include national seed collections, private collections such as research centre collections, or seeds kept in small refrigeration units in research labs. GR users therefore access the MLS to find the resource they want and to identify the *ex-situ* collection in which the resource is stored. These users then make contact with the collection to access the GR through a standard material transfer agreement (explained in Section 2.7.2 of this chapter) that contains the conditions for access as well as the distribution of benefits.

3. The ABS system of the WHO

3.1 Background

The Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits was adopted by 194 countries of the World Health Assembly in May 2011. It is generally known as the PIP Framework. It was created in response to the need to increase access to vaccines after the world faced outbreaks of H5N1

[56] Such related information refers to the 'passport information', consisting of detailed information about the samples stored in a gene bank. The minimum required passport data may include the following:
a) Samples from collecting missions: Common crop name and/or genus and species, collecting number, location of collecting site, country of origin, collecting date, phenology, collecting source and number of plants sampled.
b) Samples received as donations: Common crop name and/or genus and species, accession name and/or other identification associated with the sample, pedigree information and breeding institute's details (for breeding lines), phenology, acquisition source, country of origin, and donor accession number (if applicable).
More information available in: Crop Genebank Knowledge Base 'Registration' <http://cropgenebank.sgrp.cgiar.org/index.php/procedures-mainmenu-242/registration-mainmenu-195> accessed 2 April 2017

[57] International Treaty on Plant Genetic Resources for Food and Agriculture (n 18), Article 11.2

[58] ibid, Article 11.5

[59] ibid, Articles 11.2 and 11.3

[60] Web site of the Treaty: FAO, 'The International Treaty on Plant Genetic Resources for Food and Agriculture. Easy-SMTA Homepage' <https://mls.planttreaty.org/itt/> accessed 22 October 2017.

influenza cases in 2006. Nonetheless, its relationship with the CBD goes back to the NP negotiations.

Access to pathogens was raised for the first time by the US during the ABS 7. From then on, a number of developed countries have requested the acknowledgment of ongoing related work in various forums including the WHO.[61] They suggested excluding pathogens from the ABS system of the CBD and regulating their access through other organisations or conventions.[62] Their claims were based on two principal arguments. First, in their opinion, there was no need for the NP to regulate issues already in discussion in other negotiating forums. Second, they claimed that human-health related concerns should be addressed exclusively by the WHO.[63]

For their part, developing countries pointed out that pathogens are the raw material for vaccines. Based on this, they argued that the real intention of developed countries was not to discuss access to pathogens in connection with human-health related concerns, but to exclude a highly-profitable sector from the obligation to distribute benefits.[64]

As with other topics, no agreement could be reached on this matter. For this reason, the NP is limited to mentioning in its Preamble 'the importance of ensuring access to human pathogens for public health preparedness and response purposes' and to 'acknowledging ongoing work in other international forums relating to access and benefit-sharing.'

3.2 The WHO ABS process

The PIP Framework establishes among countries, national laboratories, vaccine manufacturers, and the WHO the responsibility of sharing biological materials[65] and contributing to a global ABS system. This system seeks to provide equitable access to vaccines, surveillance and risk assessment information, transfer of technology, skills and know-how, technical assistance, and help with building domestic capacities to respond to pandemic influenza.[66]

[61] Stefan Jungcurt and others, 'Summary of the Resumed Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 10-16 July 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 19 July 2010, vol 9, n 527), 4.
[62] ibid 5, 8.
[63] ibid 15.
[64] ibid
[65] According to the PIP Preparedness these pandemic influenza preparedness biological materials or PIP biological materials includes human clinical specimens, virus isolates of wild type human H5N1 and other influenza viruses with human pandemic potential; and modified viruses prepared from H5N1 and/or other influenza viruses with human pandemic potential developed by WHO GISRS laboratories, these being candidate vaccine viruses generated by reverse genetics and/or high growth re-assortment and the RNA extracted from wild-type H5N1 and other human influenza viruses with human pandemic potential and cDNA that encompass the entire coding region of one or more viral genes.
WHO, Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (2011).
[66] Seasonal Influenza is a common disease that can sometimes cause epidemics with different degrees of severity. Pandemic influenza is rare, and its appearance cannot be predicted. It occurs when humanity faces a new flu virus for which there is no pre-existing immunity defence. This is why, during the epidemic time, pharmaceutical

It uses Standard Material Transfer Agreements (SMTAs) for the transfer of materials and the distribution of benefits. These instruments consist of legally-binding agreements between the WHO and parties receiving biological samples. They aim to ensure that all the parties involved commit to sharing the benefits derived from access. In this way, the WHO ensures its access to vaccines, antivirals, and other supplies at the time of a pandemic.[67] In other words, the PIP Framework serves to coordinate the delivery of biological materials for the production of vaccines and the distribution of the vaccines produced.

The benefit for the provider is to receive vaccines, while for the user it is the access to the pathogens that allow the production of vaccines they can later sell, and for the WHO to ensure a proper provision of vaccines required to address a pandemic situation.

The relationship between the ABS systems of the CBD and the WHO can be established through the application of Article 4.4 of the NP. This article establishes that the Protocol does not apply 'for the Party or Parties to the specialised instrument in respect of the specific genetic resource covered by and for the purpose of the specialised instrument.' From this it can be deduced that (i) there is more than one international treaty addressing access to GR; and (ii) the Protocol does not apply in cases where there is a treaty governing access to GR for particular conditions. It can also be deduced that the ABS system of the CBD does not apply for access to GR (i) regulated by the PIP Framework, (ii) to address a pandemic situation. It may, therefore, be concluded that access to GR used to develop vaccines outside the PIP Framework and/or outside a pandemic situation should be conducted through the ABS system of the CBD.

In spite of this, for authors such as Adachi and others, the language employed in Article 4.3 of the NP[68] 'serves as a reminder that unless specifically excepted by a separate treaty, the ABS system established by the Protocol may be interpreted by courts to cover influenza viruses.'[69] Nonetheless, in the application of the *lex specialis* principle, this thesis argues that the ABS system of the CBD does not apply in the areas regulated by the WHO. Consequently, contrary to what Adachi and others express, the CBD does not cover the distribution of the benefits derived from the use of GR for the production of vaccines in a pandemic situation.

With regard to TK, it might be expected that since the scheme of distribution of benefits under the PIP Framework is intended for the production of vaccines resulting from the study

intervention is crucial to stop the disease. What is more, for the creation of vaccines the sharing of the relevant viruses as well as the benefits derived from sharing these materials is required.

[67] WHO, 'Addressing Our Health Responsibilities for Pandemic Influenza Preparedness' <http://www.who.int/influenza/pip/WHO_PIP_brochure.pdf> accessed 15 October 2016, 3-4.

[68] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (adopted 29 October 2010, entered into force 12 October 2014) A-30619 UNTS (Nagoya Protocol).

'Article 4.3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.'

[69] Kiyoshi Adachi and others, *The Convention on Biodiversity and the Nagoya Protocol: Intellectual Property Implications. A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property*, (United Nations Conference on Trade and Development UNCTAD 2014), 40.

of biological material in laboratories, the manufacture of such products does not include the use of TK and, therefore, in this context there is no room for ABS claims from ILCs.

However, although the use of TK for the development of these vaccines is highly unlikely, it is a situation that could eventually happen. In such a situation, ILCs are entitled to compensation because this right is due every time a TK is used. Moreover, such a payment must be made in accordance with the laws of the country of origin of ILCs.

4. Complementarity between the ABS Process in the CBD, the FAO and the WHO

As stated in the introduction, this chapter argues that the ABS systems of the CBD, FAO, and WHO are complementary and mutually supportive instead of opposing and overlapping, as some claim. Each regulates access to and utilisation of GR and TK in specific contexts. The CBD governs general GR and TK for general uses, the FAO regulates plant GR for food and agriculture, and the WHO regulates pathogens for the production of vaccines in a pandemic situation. Based on the content of the Vienna Convention on the Law of Treaties of 1969 and the application of the *lex specialis* principle,[70] there seems to be no doubt that the CBD does not apply to the special situations regulated by the FAO and the WHO. In the same way, it appears clear that the CBD must be used for all general cases, including those not covered by the ABS systems of the FAO and the WHO.

Consequently, an ABS process under the CBD should be conducted for access to:

i. GR not included in Annex I of the ITPGRFA;
ii. GR included in Annex I of the ITPGRFA, when used for purposes other than food and agriculture;
iii. Pathogens not accessed through the PIP Framework; and
iv. Pathogens used for vaccine production outside a pandemic situation.

Regarding PIC and MAT, it should be remembered that PIC is only mandatory for the development of ABS processes under the CBD. However, within all three systems the

[70] Although the Vienna Convention on the Law of Treaties (VCLT) does not contain a specific clause for the implementation of the *lex specialis* principle, in the opinion of some scholars, in the VCLT this principle is implemented through specific provisions many of which contain caveats, such as 'unless the treaty otherwise provides'. From there it may be argued that the application of the clauses of a special treaty on a subject matter should prevail over the application of the clauses of a general treaty on the same subject matter. Similarly, the principle according to which *lex specialis derogat lege generali* is a widely accepted maxim of legal interpretation, used for the resolution of normative conflicts, including, treaty interpretation. Hence, in this case, the effect of combining the VCLT with the *lex specialis* principle, is that the CBD can be seen as the general rule of ABS and the International Treaty of FAO and the PIP Framework of WHO as the special rules governing ABS transactions for the use of specific GR.
See for example, Christian Tams, 'The Oxford Guide to Treaty Symposium: The General Law of Treaties and its Limits' (Opinio Juris, 12 November 2012) http://opiniojuris.org/2012/11/12/the-oxford-guide-to-treaties-symposium-the-general-law-of-treaties-and-its-limits/ accessed 22 August 2018; Ahmad Ali, 'Determining Hierarchy Between Conflicting Treaties: Are there vertical rules in the horizontal system?' (2012) 2 Asian Journal of International Law 1,18.

distribution of benefits is an obligation to be fulfilled on the basis of mutually agreed terms (MATs), also called standard material transfer agreements (SMTA) within the FAO and the WHO.

In general terms, these three systems provide that access to GR shall be facilitated, that TK should be protected, and that countries of origin and ILCs have the right to benefit from the utilisation of their resources. Finally, despite the fact that using TK for vaccine production during a pandemic situation is unlikely, if it happens, ILCs will have the right to benefit from the use of their TK. The CBD rules should guide the agreements on the distribution of benefits derived from the utilisation of TK, as this knowledge is not included in the PIP Framework.

From the individual analysis of these different ABS systems, it is possible to confirm that there is no contradiction between the CBD, FAO, and WHO systems. On the contrary, it could also be stated that these instruments were created with the aim of, among other things, reaching a balanced international and supportive international ABS system.

5. The relationship between the ABS systems of the CBD, FAO and WHO

This chapter is dedicated to demonstrating, through a separate explanation of the ABS systems of the FAO and WHO, that they are not contradictory, but complementary, to the CBD. It must be emphasised, however, that a distribution of benefits from the use of GR and TK can only be successfully implemented if the ABS rules are correctly applied. Otherwise, the coexistence of more than one ABS system regulating access to the same resources may hinder the distribution of benefits, as explained in Chapter 6 regarding the joint application of the CBD and TRIPS.

To better understand what happens when these systems are applied, some context for the explanations provided above may be useful. Imagine that someone wants to use a TK to develop a new product. This product has the potential to be used in the food and the pharmaceutical sectors. Also, this user needs the GR to which the TK is associated as the raw material to make the product.

What are the options for this user to conduct ABS?

The first thing to be done is to identify the ABS system which should be used. To this end, it will be necessary to determine whether the GR to be used is in Annex I of the ITPGRFA or if it is required for vaccine production during a pandemic situation. If the answer is affirmative for the first option, the MLS must be used. If affirmative for the second, the access must be conducted through the PIP Framework. Finally, if the answer to both is negative, the CBD must be used.

The following scenarios present the ways in which access could be conducted.

5.1 Scenario 1: the ABS system of the CBD

Suppose the answer to both the previous options was negative. In this case, the user must access GR and TK using the ABS system of the CBD. According to the Convention, access

to GR can be conducted *in-situ* or *ex-situ*. This is a decision for the user to make. However, access *ex-situ* can only be carried out if the GR was collected according to the CBD unless it happened before the CBD came into force. The differences between these types of access and the possible situations that this represents are described below.

5.1.1 Access to GR *in-situ*

The process starts with the request for access to GR to the competent authority of the country of origin of the GR. To that end, since the distribution of benefits depends on it, the user must provide all the information related to the intended uses of the GR. Once permission for access is granted and an agreement has been reached, the terms for access and the way in which the benefits will be distributed should be recorded in a MAT. If the access was requested only for research, the user has an obligation to provide information about the future commercial applications, as well as reach a new MAT to distribute the commercial benefits. Nevertheless, such an obligation also exists in the event of access for commercial purposes. In other words, the provider has the right to benefit every time their resources are used. This is why the user must inform the provider about the different uses and benefits derived from such utilisation. Moreover, this may also explain why the user is not usually allowed to share samples of the GR with other people.

In this case, access is requested for manufacturing a product. Therefore, it is expected that the MAT includes the sharing of monetary and non-monetary benefits with the country of origin.

Once a MAT has been concluded, its obligations are mandatory for the parties. Hence, the provider has a duty to provide access to the GR and the right to benefit from its utilisation, and the user has the right to access the resource and the obligation to share the benefits they gain from its use.

5.1.2 Access to GR *ex-situ*

In theory, the only difference between access *in-situ* and access *ex-situ* is the provider of GR. In the first case, it is a country of origin, and in the second it is an *ex-situ* conservation centre. For this reason, it is expected that the countries of origin also benefit from the use of their resources when accessed in *ex-situ* conditions. However, this does not seem to be happening.

As explained earlier, access *ex-situ* means, for example, access through a collection. This should not be a problem. However, for a long time, collections were operating under the mandate of the CGIAR which promoted the free sharing of GR and their associated information for research.[71] Furthermore, the sharing of GR and their related information is a common

[71] Cullet (n 9) 2-3.

practice developed by collections using the MTA adopted by the FAO with Resolution 1/2006.[72] In addition, MTAs are usually implemented using the FAO 'International Code of Conduct for Plant Germplasm Collecting and Transfer' which contains voluntary guidelines to access GR in *ex-situ* conditions. The problem caused by the application of this Code in ABS transactions is that it refers to the countries of origin as 'donors' of GR.[73] Although the Code recognises the need to promote the sharing of benefits between users and donors,[74] there is a risk that the word 'donor' may perhaps evoke the idea of giving something for free. In this way, access to GR *ex-situ* maintains the idea of access without the need for benefit-sharing.

Moreover, *ex-situ* conservation centres have allegedly not fully implemented the CBD.[75] Consequently, in a relationship which does not include the countries of origin, they continue to share GR in exchange for information with the collection, regardless of whether: (i) this GR is in Annex I of the FAO International Treaty; (ii) if their use will be exclusively in the fields of food and agriculture; and (iii) whether they were collected before or according to the CBD. Apparently, users are not asking for this information. It also appears they do not mind that only a few GR can be accessed for free and that they cannot be used for any purpose. Given the above, it seems that is the incorrect application of the ABS systems that is undermining the distribution of benefits rather than their joint application.

Under these conditions, it is highly probably that users are accessing the GR they need without having complied with the obligations of PIC, MAT, or the distribution of benefits as stipulated in the CBD.

5.1.3 Access to TK

TK should be accessed conducting PIC, MAT, and the distribution of benefits. This process is the same regardless of whether the GR to which TK is associated was accessed in *in-situ* or *ex-situ* conditions. The benefits from the utilisation of TK should be shared with the ILC who developed and/or maintained the knowledge. Also, this community is the only one entitled to grant PIC. Therefore, the first step in accessing TK is the identification of the ILCs to which such a TK belongs.

Accessing TK should be developed following the national laws of the given country and the customary laws and protocols of the ILCs. However, sometimes ILCs' customary law is not written. This could create uncertainty for the user about the proper procedures to follow. As a consequence, some users may be less motivated to conduct processes to access TK and this could therefore be perceived as an obstacle for the distribution of benefits to ILCs.

In addition, much TK is accessible to the public. As explained in the Section 3.2.4 of Chapter 4, this has led to the erroneous assumption that this TK is in the public domain and

[72] Several *ex-situ* collections and research centres operate using the MTA established by the FAO. See for example: Crop Genebank Knowledge Base (n 39)
[73] FAO, 'International Code of Conduct for Plant Germplasm Collecting and Transfer' (n 40), Article 2.1
[74] ibid, Article 1.7
[75] Watanabe (n 24) 548.

therefore is free to use without generating obligations of PIC and the distribution of benefits to ILCs.

Therefore, although in theory ILCs have the right to benefit from the use of their TK, what could be happening is that the user knew about the existence of the TK because it is publicly accessible. Hence, it is very likely that such a user will not carry out an ABS process to access such a TK because access has already been gained. This leads to the conclusion that access to publicly-available TK should be regulated, otherwise ILCs will not benefit from the utilisation of a large proportion of their TK.

5.2 Scenario 2: the FAO ABS system

Access must be conducted through the MLS when the GR is listed in Annex I of the ITPGRFA and will be used for food and agriculture, or for the use of GR collected before the CBD came into force. This last aspect can only be clarified by the *ex-situ* conservation centre.

The MLS is not clear about the way in which ILCs can benefit from the use of their TK. The system does not contain a single article specifying how the benefits should be distributed when TK is accessed. Nevertheless, the countries' right to regulate access to plant GR for food and agriculture is established in Article 10. Users should, therefore, follow the national legislation of the collection in those cases where access to associated TK has been regulated by a party to the ITPGRFA. Seemingly, the national approach to compliance hinders ABS, and in this particular case, the rights of ILCs to benefit from the use of their TK.

5.3 Scenario 3: the WHO ABS system

The task of recognising when the PIP Framework must be used is easier. The factor unequivocally indicating this point is when the world faces a pandemic situation. In such circumstances, countries and companies around the world will work together under the direction of the WHO to produce sufficient vaccine to control the situation. This is not the hypothetical situation presented above and, hence, this ABS system would not apply.

The PIP Framework was adopted after the outbreaks of H5N1 influenza cases in 2006, meaning that its scope is precise. This also may explain why it was designed to allow a fast and efficient response to control pandemic situations.

This fact is crucial, as Article 4.4 of the Protocol limits its application to the existence of a 'specialised instrument in respect of the specific genetic resource covered by and for the purpose of the specialised instrument.' As noted, the main elements of this article are a specialised instrument that regulates the use of specific GR for a precise purpose. It follows that if these conditions do not apply, the ABS system of the CBD should be applied. In other words, vaccine production happening outside a pandemic situation should be addressed using the CBD.

5.4 Final remarks

This section aims to illustrate the explanations given above through one example. Although it describes a hypothetical situation, the course of the events demonstrates some of the most frequent criticisms related to the unauthorised access of GR and TK, often called biopiracy.[76]

Based on this, it is possible to affirm that there is no conflict between the ABS systems of the CBD, FAO, and WHO. Instead, as noted by Watanabe, what appears to be happening is that access to GR is mainly conducted in *ex-situ* conditions,[77] and, as pointed out by Davis and others, that *ex-situ* collections have not integrated the ABS system of the CBD into their practices.[78] This might be because they work under the CGIAR logic in which GR are apparently freely accessed and shared.

6. Conclusions

The CBD is not the only international treaty governing the distribution of benefits derived from the utilisation of GR and TK. The FAO and WHO also contain ABS systems. Together, the CBD, FAO, and WHO comprise the international ABS system. These systems were created to complement each other. Because of this, they regulate ABS within a particular scope and therefore do not overlap, contradict, or oppose each other. The scope of the MLS is the utilisation of plant GR listed in Annex I of the ITPGRFA for food and agriculture purposes, and GR collected before the CBD. The scope of the PIP Framework is the utilisation of pathogens and viruses for vaccine production in a pandemic situation. Finally, the general rule of the CBD ABS system is that it does not apply to situations ruled by a specialised instrument. In this way, access to GR and its associated TK, which is not included within the scope of the FAO or WHO, ABS systems should be conducted using the CBD.

However, it appears that access to all kinds of GR *ex-situ* (not only those listed in Annex I of the ITPGRFA) for all kind of uses (not only for food and agriculture) is being conducted within the FAO ABS system. This situation, together with the fact that the CBD does not regulate access *ex-situ*, may be the cause of one of the principal problems in achieving the distribution of benefits. This is particularly because indications suggest that GR is mainly accessed in *ex-situ* conditions. (This idea is developed in Chapters 3 and 6.)

Similarly, it seems that access to GR for vaccine production outside a pandemic situation is not happening through the ABS systems of WHO or the CBD. As indicated, some countries opposed the inclusion of pathogens and viruses within the scope of the CBD. As a result, it was agreed that access and utilisation of these resources would be addressed within the WHO. That is why the PIP Framework was created. However, this system only applies to

[76] See for example: Sociedad Peruana de Derecho Ambiental, 'Documentos de Investigación' <http://www.spda.org.pe/publicaciones/documentos-de-investigacion/> accessed 3 October 2016.
[77] Watanabe (n 24) 549.
[78] Davis and others (n 27) 152.

access to GR for vaccine production during a pandemic situation. The practical consequence of this is that access to and utilisation of pathogens and viruses in a non-pandemic situation are conducted outside the ABS rules of the WHO and the CBD. This is another big gap in ABS.

CHAPTER 6. The relationship between ABS and Intellectual Property Rights (IPRs)

1. Introduction

Chapters 3, 4, and 5 explained the ABS design, content, scope, functioning, and the relationship between the CBD and the ABS systems of FAO and WHO, which constitute the international ABS system. It was concluded that flaws in all those dimensions could be the cause for the scarce distribution of benefits.

In spite of this, criticism is mainly reduced to pointing out that the exercise of Intellectual Property Rights (IPRs) is the primary reason for the lack of compliance with ABS. For this reason, this chapter explores the relationship between ABS and IPRs with a view to understanding the way in which the exercise of IPRs could be another cause that undermines the distribution of benefits. In doing so, the chapter first explains the lack of parity between ABS and IP, using theories of fragmentation and complexity in international law. Here, it is concluded that, although the CBD and IP norms do not formally contradict each other, the non-integration of the ABS rules within the procedures for granting IPRs over creations using GR and TK may affect the distribution of benefits. Following that, an overview of biodiversity and TK utilisation is provided to give a general view about their value. Finally, a synopsis of the main proposals for the joint exercise of ABS and IPRs is provided.

The chapter concludes that the failure to integrate ABS in the IP system could affect the functional effectiveness of ABS, because this flaw makes it possible to obtain IPRs over creations using GR and TK without conducting ABS and without distributing the benefits derived from such utilisation. Another conclusion is that due to fragmentation and the complexity of the international system of ABS, the distribution of benefits seems very hard to achieve. Consequently, a global solution is a good option for tackling these particular issues.

2. TRIPS and CBD

The first and most conspicuous thing that can be noted about ABS is that the relationship between TRIPS and the CBD is highly problematic. Several and opposite positions can be found in the academic literature explaining, for example, their interconnections and the possible causes for the difficulties of their joint implementation. In contrast to what happens with the matters studied in Chapters 3, 4, and 5, the amount and vast array of information that can be found in this regard makes the presentation of this topic a difficult task. However, to introduce it to the reader, a summary of the most important points is presented below, along with a delimitation of its analysis.

There is a general trend towards identifying the relationship between TRIPS and the CBD by matching such a relationship with the interests and expectations of providers and users of GR and TK regarding the distribution of benefits. For this reason, providers and users are often considered as two different parties in the same affair. In such a way, developing countries

are viewed as the providers and developed countries (more precisely, the private sector businesses and scientific research institutions within their jurisdictions) as the users of GR and TK. Of course, there are exceptions. For example, Australia is a developed country rich in biodiversity, whilst Brazil is a developing country that is biotechnologically developed with important agro-industrial capacities.[1] Moreover, the range and depth of concerns regarding ABS cover different stakeholders (for example, countries, private sector, ILCs, and NGOs) and many views about the way in which biodiversity can be used (for instance, for human development, equity and justice, the ecological relationships upon which sustainable development must be built, health, agriculture, or technology). These factors open a broad range of possibilities and relationships to make ABS even more challenging to achieve.[2]

Notwithstanding the possibility that providers and users are not always a developing and a developed country respectively, the analysis presented in this work was not elaborated on a case-by-case basis. Therefore, although it is acknowledged that the roles of provider and user have different nuances, in this thesis the party providing a resource is referred to as the provider, and the party using a resource is described as the user. It is also recognised that in most cases, providers are in developing countries and users are mainly located in developed countries. Hence, in general, the terms provider and user can typically be regarded as connoting developing and developed countries respectively, and, therefore, these terms are mutually interchangeable in this thesis.

The relationship between TRIPS and the CBD is usually described as conflicting. Nonetheless, such allegations should be clarified as drawing a line between legal and policy conflicts. In terms of form, it is possible to affirm that laws rarely conflict in the sense of two rules contradicting one to another. Thus, no rule in TRIPS contradicts the CBD. Moreover, the principles and objectives of TRIPS seem to support ABS compliance. However, unlike laws, legal principles can stand in tension with another. For instance, it is often affirmed that the principle of national sovereignty over GR in the CBD is in tension with the principle in TRIPS that IPRs are private property. In other words, it is stated that TRIPS and the CBD are in conflict because they concede at the same time two different kind of property rights over an identical subject matter—sovereign and private rights over GR. While this may be true, it seems that it is not the existence of sovereign and private rights over GR and associated TK which causes the inoperability of ABS, but the fact that the absence of compliance with ABS does not affect the concession of IPRs.

In this respect, the discussion has been focused on the extent TRIPS violates and/or undermines ABS, and, therefore, if an amendment to the Agreement is required. Accordingly, the incorporation of rules for compliance with ABS in the legal procedure for the concession of IPRs will depend on the policies adopted by each Member State of the WTO and the CBD. It

[1] Charles Victor Barber, Sam Johnston and Brendan Tobin, 'User Measures. Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity' (UNU-IAS-Report, 2nd edn 2003).

[2] DG TRADE European Commission, CEAS Consultants (Wye) Ltd Centre for European Agricultural Studies, Geoff Tansey, and Queen Mary Intellectual Property Research Institute, 'Study on the Relationship Between the Agreement on TRIPS and Biodiversity Related Issues. Final Report' (CEAS, September 2000), 55.

can be noted in this regard that, for example, some countries have incorporated disclosure requirements for patent applications in their national laws and others have not.[3] Nevertheless, these different approaches produce diversification of the requirements and conditions for the granting of IPRs as well as problems of compliance with ABS within different jurisdictions. This is because someone can, at the same time, be acting in compliance with the law of the country granting a patent right, but against the legislation of the country of origin of the GR and TK with respect to the use of such resources in the invention that has been protected with such a patent right.

In addition to what is expressed above, it should be highlighted that the relationship between TRIPS and the CBD is not limited to the legal level. In fact, the content and scope of the rights they recognise have been shaped in the political sphere. More precisely, the rights ultimately envisaged in TRIPS and the CBD were simultaneously developed in different fora in which many interconnected topics were discussed. Nevertheless, despite the multiplicity of interests expressed, it is possible to identify a common concern in TRIPS and the CBD: the regulation of access to and utilisation of natural resources. Two positions can be clearly seen in this regard. On the one hand, an interest for controlled access to biodiversity and the distribution of benefits derived from its utilisation. On the other hand, a demand for facilitated access to biological diversity, with an obligation to distribute benefits limited exclusively to the use of biological material containing units of heredity. To some extent, the CBD and TRIPS envisage these positions.

Finally, although conflicts between TRIPS and the CBD should be resolved at the legal level, this is a subject matter so highly politicised that a legal solution might not be easy to achieve. This thesis acknowledges this fact as a limitation for the amendment of flaws in the CBD and the NP. Thus, with the aim to provide an overall picture of the obstacles posed from the international/political dimension of ABS, the following two sections contain information regarding some of the difficulties found in the application of international law.

2.1 The International Arena

Tensions between TRIPS and the CBD are a recurrent topic in the analysis of compliance with ABS. On this subject, it is commonly affirmed that one of the factors affecting the application of ABS is that the CBD overlaps with other international treaties regulating GR and TK utilisation. Therefore, the rules of the instruments comprising the international ABS system[4] create multiple and different requisites and approaches towards the distribution of benefits,

[3] For example, disclosure is an obligation under the legislation of the countries of the Andean Community of Nations, Costa Rica and Brazil, while, for European countries, disclosure by patent applicants is encouraged but not obligatory.
Alison Hoare and Richard Tarasofsky, 'Asking and Telling: Can "Disclosure of Origin" Requirements in Patent Applications Make a Difference?' (2007) 10 The Journal of World Intellectual Property 149, 152, 155-156.

[4] As explained in Chapter 5, these instruments are: the CBD, the Nagoya Protocol to the CBD, the International Treaty on Plan Genetic Resources for Food and Agriculture (ITPGRFA) of the FAO, and the Pandemic Influenza Preparedness (PIP) Framework of the WHO.

which result in the inoperability of ABS. Despite these allegations, this thesis has shown in Chapter 5 that the norms of the international ABS system do not contradict or overlap. This can be seen, for example, in the way they cross-reference each other. Nevertheless, many studies about the functioning of international law have concluded that responses composed of more than one international treaty might be difficult to implement. Thus, at the international level, ABS failure might be caused not because the norms that comprise the international system contradict and overlap, but because ABS has been fragmented in more than one international instrument.

ABS is a fragmented system. Fragmentation of international law is a phenomenon considered as one of the most serious sources of conflict between treaty regimes.[5] As noted by Jenks, fragmented systems are the result of a law-making process in which treaties are developed 'in a number of historical, functional and regional groups which are separate from each other and whose mutual relationships are in some respects analogous to those of separate systems of municipal law.'[6] For Fischer-Lescano and Teubner, such a process led to the so-called 'functional differentiation' consisting of the emergence at the international level of specialised and relatively autonomous rules, legal institutions, and spheres of legal practice, each possessing their own principles and institutions.[7] In the opinion of Koskenniemi, the practical effect is that conflicts emerge between rules and rule-systems, which divert institutional actions and produce the loss of an overall perspective on the law.[8]

Furthermore, overlapping systems are considered as 'regime complexes'. A regime is complex when 'a network of three or more international regimes that relate to a common subject matter; exhibit overlapping membership; and generate substantive, normative, or operative interactions recognised as potentially problematic whether or not they are managed effectively.'[9] Accordingly, difficulties in the operability of complex regimes are the result of their overlapping, regardless of whether their norms contradict each other or not; because, as a result of this overlapping, a wide range of organisations[10] with general, functional, or regional responsibilities are created.[11] The production of the legislative instruments for ratification or acceptance by states is one of the responsibilities of these organisations; the way in which they interact to produce such instruments is one of the causes for the inoperability of complex regimes, rather than the overlapping which characterises this kind of system.[12] According to

[5] Wilfred Jenks, 'The Conflict of Law-Making Treaties' (1953) 30 BYBIL 401, 403 in UN, General Assembly, International Law Commission, 'Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law. Report of the Study Group of the International Law Commission, Finalised by Martti Koskenniemi' (2006) A/CN.4/L.682, 10.

[6] ibid

[7] Andreas Fischer-Lescano and Gunther Teubner, 'Regime-Collisions: the vain search for legal unity in the fragmentation of global law' (2004) 25 Michigan Journal of International Law 999 in UN (n 32) 11.

[8] UN (n 5) 11.

[9] Amandine Orsini, Jean-Frédéric Morin and Oran Young, 'Regime complexes - a buzz, a boom or a boost?' (2013) 19 Global Governance 27, 29.

[10] In the case of ABS, these institutions are not only created between the organisations dealing directly with an ABS system, but also within the WIPO and WTO.

[11] Jenks (n 5) 403.

[12] ibid

Orsini, Morin, and Young, the interplay between these organisations leads to mutual adjustments having the potential to generate beneficial or negative cooperative relationships among the common Parties of the international treaties comprising the regime complex.[13] In this respect, these authors understand that interplay can change global governance[14] by 'strengthening the power asymmetries to favour the already powerful players' which affects the functionality of the regime.[15]

It follows from this that the operability of fragmented and complex regimes is not totally determined by the content of the legal instruments of the regime, but largely delimitated by the interplay of their institutions. In this vein, studies on fragmentation and complexity have concluded that the divergence of rules across systems constitutes a major source of transnational conflict. Regarding the food security regime, it has been noted, for example, that fragmentation leads to the practical consequence of inefficiency in solving the problem for which it was created, namely, global hunger.[16]

For this reason, one of the biggest concerns in this matter is how easy or difficult it is to resolve or manage the transnational problems derived from the application of fragmented and complex regimes. For authors such as Robert, Keohane, and David, complexity facilitates flexibility and renovation of the architecture of governance which simplifies its organisation,[17] while for Struett and others complexity is harmful to global governance.[18]

Regardless of the position taken on this problem, it should also be considered that the instruments comprising a complex regime do not exhibit hierarchical relations, otherwise, their interactions would not be problematic. Furthermore, it should be noted that the jurisdiction of most international tribunals is limited to particular types of disputes or disputes arising under particular treaties.

Accordingly, one of the major obstacles for the implementation of fragmented and complex regimes is the absence of a mechanism that allows the Parties to solve the transnational problems of the system at the international level rather than in national or regional spheres. Because of this, and with the aim to contribute to a solution for the lack of distribution of benefits derived from the use of GR and TK, from a legal perspective, Chapter 7 contains a proposal of key elements that could be used for ABS implementation.

[13] Orsini, Morin and Young (n 9) 28, 34.

[14] ibid 34.

'Governance is the sum of many ways individuals and institutions, public and private, manage their common affairs. It is a continuing process through which conflicting or diverse interests may be accommodated and co-operative action taken. It includes formal institutions and regimes empowered to enforce compliance, as well as informal arrangements that people and institutions either have agreed to or perceive to be in their interest.' Peter Hägel, Global Governance (2011).

[15] Orsini, Morin and Young (n 9) 34-35.

[16] Matias Margulis, 'The Regime Complex for Food Security: Implications for the Global Hunger Challenge' (2013) 19 Global Governance 53, in Orsini, Morin and Young (n 9) 34.

[17] ibid

[18] Michael Struett, Mark Nance and Diane Armstrong, 'Navigating the Maritime Piracy Regime Complex' (2013) 19 Global Governance 93, in Orsini, Morin and Young (n 9) 34.

2.2 The legal relationship between TRIPS and the CBD

As mentioned before, while TRIPS and the CBD do not conflict in a strictly legal sense, national or regional policy conflicts do arise out of their implementation.[19] On this matter it is consistently affirmed that Article 27.3b of TRIPS, on patentability or non-patentability of plant and animal inventions and the protection of plant varieties, is the point connecting IPRs with the CBD. Allegedly, there is a strong likelihood of granting IP rights on inventions using GR and TK that do not comply with the ABS obligations. As a result, since the WTO Ministerial Conference in Doha in 2001, the protection of TK and the relationship between ABS and IP began to be considered within the WTO. Thus, Paragraph 19 of the 2001 Doha Declaration broadens the scope of the effects of TRIPS beyond IPRs when requesting an analysis on its relationship with the CBD and the protection of TK and folklore. Furthermore, it was stated that such a task shall be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8).[20]

Within the TRIPS Council, State Members seek the implementation of TRIPS and the CBD in a mutually supportive manner. To that end, the content of Articles 16.5 of the CBD and 17 of the Nagoya Protocol have been considered. The former provides that Contracting Parties should cooperate to ensure that IPRs are supportive and do not run against the CBD objectives. The latter establishes that State Members should take measures to monitor and enhance transparency concerning the utilisation of GR, including designating effective checkpoints to collect or receive relevant information at any stage of research, development, innovation, pre-commercialisation, or commercialisation. Patent offices have been suggested as checkpoints as a way to know the use made of GR and TK in jurisdictions other than in countries of origin.

As a result of these meetings, the need to disclose the origin of GR and TK used in the invention for which protection is sought in patent applications is a topic under current analysis by the Members of the WTO. This idea was drawn up on the confidence that a legal obligation establishing this requirement in patent applications would contribute to preventing both misappropriation of GR and TK, and the erroneous granting of patents.[21] It was consequently affirmed that a disclosure requirement would enhance transparency about the utilisation of GR and TK, and compliance with patentability criteria that has frequently been criticised for

[19] DG TRADE European Commission, CEAS Consultants (Wye) Ltd Centre for European Agricultural Studies, Geoff Tansey, and Queen Mary Intellectual Property Research Institute, 'Study on the Relationship Between the Agreement on TRIPS and Biodiversity Related Issues. Final Report' (CEAS, September 2000), 75.

[20] WTO, 'Doha Ministerial Declaration' (2001) WT/MIN(01)/DEC/1. Paragraph 19:
We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.

[21] WTO, Council for Trade-Related Aspects of Intellectual Property Rights, 'The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity. Summary of Issues Raised and Points Made' (2006) IP/C/W/368/Rev.1, 27-34.

allegedly being applied with too little rigor when the use of TK is involved.[22] An opposite view was expressed that no amendment to the patent system is needed because the problems derived from the CBD application can be solved using contract law and the strengthening of the national laws on ABS.[23] These two positions constitute the basis for the current negotiation taking place within the WIPO, of one or more international instruments relating to IP that will ensure the balanced and effective protection of GR, TK and traditional cultural expressions. The content of these proposals is explained in more detail in Section 4 of this chapter.

3. The use of Biodiversity and TK

For Groth, the value of biodiversity and the role of TK in biodiversity preservation and the maintenance of culture and identity are undervalued in international negotiations. He points out, as an example of this, the way in which the policy objectives and core principles for both the protection of TK and traditional cultural expressions have been drafted was negotiated within the WIPO.[24] Indeed, poor valuation of GR and TK has the potential to affect the negotiations on the distribution of benefits derived from the use of these resources. In fact, GR and TK are often valued only in economic terms, equated with raw materials that have little or no value, whilst their biological and cultural dimensions seem to be disregarded in such valuation (see Section 5.2.4 of Chapter 4). In this regard, this section aims to demonstrate that GR and TK are of value and are widely used by industry and commerce. It is expected that the data presented below can overcome the possible doubts about the value of these resources as well as the right of providers to benefit from the use of them.

3.1 The use of biodiversity and TK in health services

Biodiversity and TK directly relate to the fundamental rights of life and health of poor populations in developing countries. Concerning this, the WHO has pointed out that TK replaces the usual means of supplying medical services for ILCs in developing countries, which would otherwise be provided by hospitals and medicines. As an example, the ratio of traditional healers to the population in Africa is 1:500 whereas the ratio of medical doctors to population is 1:40.000. Thus, for millions of people in rural areas, traditional healers and traditional medical knowledge[25] remain their primary source of health services.[26] In the same

[22] ibid
[23] ibid 14-16.
[24] Stefan Groth, Negotiating Tradition. The Pragmatics of International Deliberations on Cultural Property (Göttingen Studies in Cultural Property, vol 4, Universitätsverlag Göttingen, 2012), 157.
[25] According to the World Health Organisation traditional medicine is 'the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health and in the prevention, diagnosis, improvement or treatment of physical and mental illness' that 'covers a wide variety of therapies and practices which vary from country to country and region to region' and 'in some countries, it is referred to as "alternative" or "complementary" medicine (CAM).' WHO, 'Traditional and Complementary Medicine' <http://www.who.int/topics/traditional_medicine/en/> accessed 19 November 2015
[26] WHO, WHO Traditional Medicine Strategy: 2014-2023 (WHO 2013), 27.

direction, the United Nations Conference on Trade and Development (UNCTAD) has stressed that the use of traditional medical knowledge by the poorest segments of developing countries has major repercussions, due to the fact that 'modern medicine is unlikely to be a realistic treatment option'.[27] The UNCTAD observes that in contrast to the difficulties of accessing modern medicine, traditional medicine is widely available, even in remote areas, which results in its large-scale use, as is the case in India and Africa, where it is utilised by 70% and 80% of the population respectively.[28]

Notwithstanding the above, the use of traditional medical knowledge is not exclusive to developing countries. According to the WHO, this is because this kind of TK can be found in almost every country in the world and is proven to be of good quality, safe, and effective.[29] Consequently, the market for traditional medical knowledge is huge. As an illustration, over 100 million Europeans are currently users of traditional medicine, with one fifth using it regularly, and the same number preferring health care services that includes traditional medicine.[30] Among all manifestations of traditional medicine knowledge, traditional Chinese medicine is arguably the world's most widely used.[31] The market of this single service in China represented an amount estimated to $83.1 billion USD in 2012, for Korea $7.4 billion USD in 2009, and for the US, $14.8 billion USD in 2008.[32] These figures show that TK has a prominent place in the medicine market.

3.2 The use of biodiversity and TK in commerce

ten Kate and Laird concluded in 2002 that the annual market for various categories of products derived from GR was between $500 billion USD and $800 billion USD. This number includes the sectors of: pharmaceuticals $75-$150 billion USD; botanical medicines $20-$40 billion USD; agriculture produce $330-$470 billion USD; ornamental horticultural products $16-$19 billion USD; crop protection products $0.6-$3 billion USD; biotechnologies in fields other than healthcare and agriculture $60-$120 billion USD; and personal care and cosmetic products $2.8-$2.8 billion USD.[33]

More recently, Laird and Wynberg demonstrated that in 2004 there was a great demand for access to GR in five sectors: pharmaceuticals, biotechnology, seed, crop protection, and horticulture—the same sectors as in 2002. Reportedly, the pharmaceutical industry grew around 9% in 2004 from 2003, presenting gains of approximately $500 billion

[27] United Nations Conference on Trade and Development, 'Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions' Sophia Twarog and Promila Kapoor (eds) (2004) UNCTAD/DITC/TED/10, 3.
[28] ibid 3.
[29] WHO (n 26) 7.
[30] ibid 25.
[31] ibid 22.
[32] ibid 26.
[33] Kerry ten Kate and Sarah Laird, *The Commercial Use of Biodiversity. Access to Genetic Resources and Benefit-Sharing* (Earthscan Publications Ltd 2000), 2.

USD. This industry was concentrated in North America, Europe, and Japan.[34] For the same year, the biotechnology industry increased by 17% over 2003 and had revenues of $54.6 billion USD. This sector was dominated by the US with 78% of global public company revenues, followed by Europe at 14%, Canada at 4%, and the Asia-Pacific region at 4%.[35] Regarding the breeding and sale of agricultural products, the use of GR presented variations depending on the sector. For example, the seed sector was far more reliant on breeding material from its own private collections or other genebanks than from the wild, whereas the crop protection sector had a greater interest in wild GR for chemical protection or plant improvement. In this sector, ten companies controlled 49% of the global seed market in 2004. During that year, commercial seed sales were estimated at between $21 billion USD and $30 billion USD.[36] Genetically modified (GM) crops increased more than 47-fold from 1.7 million hectares in 1996 to 81 million hectares in 2004, with soya as the most commonly planted GM crop. During that year, this market was $4.70 billion USD.[37] The horticultural industry was $12.425 USD, showing an increase of 28% since 2001.[38] Fifty-five percent of the import value of the live plant trade was accounted for by Germany (20%), France (11%), the United Kingdom (8.8%), the United States (8.5%), and the Netherlands (6.5%). The export trade of live plants was dominated by the Netherlands (41%), with Denmark, Belgium, Italy, and Germany, comprising 32%.[39]

For its part, TK associated with GR has been seen as a valuable global resource. It has, for example, been acknowledged that TK contributes significantly to scientific discoveries and biotechnology development. In this field, the use of TK has reportedly allowed researchers to find and move genetic sequences responsible for particular traits in a plant, move traits from one species to another, and even isolate many molecules, which are the active compounds for agricultural and pharmaceutical uses.[40] It has also been accepted that, although the role of TK in pharmaceutical discovery was relatively small before 2000, during the following years, it grew at a slow rate.[41]

Finally, it should be said that despite the usefulness of economic studies about the use of biodiversity and TK, some flaws have been identified. For example, Pearce and Moran point out that these studies have usually been restricted to use values.[42] They note that, as a result, some ecosystems or regions are systematically left out from these analyses, while some others, such as tropical forests and wetlands, are common subjects of research.[43] Christie and others observe that the content of the questionnaires used in the studies about the value of

[34] Sarah Laird and Rachel Wynberg, *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors*, (Secretariat of the Convention on Biological Diversity, CBD Technical Series No. 38, 2008), 100.
[35] ibid 106.
[36] ibid 111.
[37] ibid 112.
[38] ibid 115.
[39] ibid 116.
[40] Tesh Dagne, 'Protecting Traditional Knowledge in International Intellectual Property Law: Imperatives for Protection and Choice of Modalities' (2014) 14 J. Marshall Rev. Intell. Prop. L. 25, 33.
[41] Laird and Wynberg (n 34) 100.
[42] David William Pearce and Dominic Moran, *The Economic Value of Biodiversity* (Earthscan Publications Ltd 1997), 85.
[43] ibid

biodiversity have limitations in literacy and language, social context and values, the validity of utilitarian assumptions, and in the design of the guidelines about how to answer the questionnaires.[44] In their view, these limitations create significant problems for the respondents who are not literate or specialist and, therefore, will not be able to read the material, to complete the questionnaire, or to express complex standpoints.[45] Lastly, Wekundah highlights the fact that the commercial use of TK has been more frequently analysed within the frame of traditional medicinal knowledge, leaving out the analysis of other aspects of this knowledge.[46]

For these reasons, despite the many studies conducted on the economic value of biodiversity and TK, more analysis is required to determine the value of those ecosystems and expressions of TK that have not yet been adequately addressed. Nonetheless, from the existing studies and data, it is possible to conclude that biodiversity and TK are valuable resources and that their protection and preservation are more than justified, of which ABS is an important part.

3.3 The use of biodiversity and TK in patent activities

There are not many studies about how GR and TK have been used in patent activities. This fact has been broadly reported as an issue in intergovernmental debates about the governance of GR, TK, and IP.[47] For that reason this section is only based on three sources reporting the use of GR and TK in patent activities.[48] Two of them analyse the use of plants, while the other is dedicated to animal GR.

Overall, these studies affirm that human societies depend upon biodiversity (plants and animals) for the fulfilment of basic needs.[49] For example, when analysing the sources of all new chemicals between 1981 and 2002, it was found that 63% were derived from some natural product, and that this number increases to 80% between 2002 and 2003.[50] However, they also indicate that patent activity is focused upon a narrow range of biological species.[51] In spite of

[44] Mike Christie and others, 'An Evaluation of Monetary and Non-monetary Techniques for Assessing the Importance of Biodiversity and Ecosystem Services in Countries with Developing Economies' (2012) 83 Ecological Economics 67, 73-75.
[45] ibid
[46] Joseph Wekundah, *Why Protect Traditional Knowledge?* (African Technology Policy Studies Network, 2012), 10.
[47] Paul Oldham, Stephen Hall and Oscar Forero, 'Biological Diversity in the Patent System' (2013) 8 PLOS ONE 1, 2.
[48] 1. Oldham, Hall and Forero (n 47).
2. WIPO Patent Landscape Report on Animal Genetic Resources (by Paul Oldham, Stephen Hall and Colin Barnes in cooperation with the Food Agriculture Organisation of the United Nations (FAO) with contributions of Irene Hoffman and Paul Boettcher (Animal Production and Health Division, FAO, 2014).
3. WIPO, 'Record Year for International Patent Applications in 2016; Strong Demand Also for Trademark and Industrial Design Protection' (2017) <www.wipo.int/pressroom/en/articles/2017/article_0002.html> accessed 31 March 2017.
[49] WIPO (n 48) 22; Luciana Costa Brandão and Júlia Paludo, 'Biodiversity and Gene Patents' (2013) 1 UFRGS Model United Nations Journal 244, 244.
[50] Costa Brandão and Paludo (n 49) 248.
[51] ibid

this, it is reported that in 1997, 10 of the 25 best-selling drugs were related to natural products, which represented 42% of all pharmaceutical industry sales for $17.5 billion broadly.[52] This led to the conclusion that, although patent activity centres on a few portions of biological diversity, the market of such products is not necessarily small. According to Oldham, Hall, and Forero, despite approximately 1% of biodiversity on the planet being used for patent purposes, global receipts from IP from creations using natural resources stood at $180 billion USD in 2009.[53]

3.3.1 Study No. 1

Without including viruses, Oldham and others carried out a study in 2013 about patent activity on biodiversity using the documents from the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), and the Patent Cooperation Treaty (PCT) for the period 1976-2010.[54] The mention of the absence of viruses in their report is important because they are the raw material for producing vaccines, which constitute an important branch of the medical market.

This study declares that 136,880 patent documents contain 25,495 species names from the 1,347,224 species listed within the Species 2000/ICTIS Catalogue of Life Annual Checklist 2011.[55] The major fields of patent applications identified in this study are pharmaceuticals/medicinal preparations, genetic engineering of foods, peptides, testing enzymes/microorganisms—DNA sequencing, analysing chemical/physical properties, and fermentation/enzyme using chemical synthesis.[56]

Some interesting conclusions can be made about the use of natural products and traditional medicines. For example, natural products play a key role in the development of approved pharmaceuticals and cosmetics,[57] the 'presence of plants in pharmaceutical preparations is strongly associated with traditional medicines as a growing area of patent activity,'[58] and the use of 12,045 plant species and 1,519 species of fungi in pharmaceutical preparations associated with traditional medicines makes this a growing area of patent activity.[59] These findings confirm the arguments of the WHO and UNCTAD in relation with the crucial role played by traditional medicine knowledge in the medical field, and also run counter to some statements asserting that natural products are a declining focus of interest for R&D.[60]

The study found two major focuses of patent activity. The first is that genetic engineering using both biotechnology and genomics as tools. In contrast with traditional medicines, biotechnology involves diversification in the patent system. That is to say, despite biotechnology (including emerging fields such as synthetic biology) focusing on a small group

[52] ibid
[53] Oldham, Hall and Forero (n 47) 9, 11.
[54] ibid 2-3.
[55] ibid 3.
[56] ibid 5.
[57] ibid 6.
[58] ibid
[59] ibid
[60] ibid 5, 6.

of species, it allows the extension of patent claims across multiple organisms sharing the evolutionary history of the species upon which the claims of the patent have been written.[61] This finding affirms the fact that there is no requirement that patent activity must relate to a larger number of species to be a profitable business.

The second major focus of patent activity is the genetic engineering of foods. Nonetheless, these authors noted that, due to the narrowness of agricultural R&D to a small number of companies, it is hard to draw final conclusions regarding the strategic importance of *in-situ* agricultural biodiversity in contrast with *ex-situ* collections under the MLS.[62]

Finally, an important feature of patent activity was identified in relation to biocides and the use of marine GR beyond national boundaries.[63]

3.3.2 Study No. 2

Study No. 2 is entitled 'Patent Landscape Report on Animal Genetic Resources'[64] and contains information on patent documents of the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), and the Patent Cooperation Treaty (PCT) from the period between 1976 and 2013. It searched for the use of 17 animal species[65] (using their Latin species names and common names) in the title, abstract, and claims of 14,038,743 patent documents,[66] to identify i) patent activity involving animals as a GR, and ii) activity involving animal breeding for food and agriculture.[67] The main conclusions of this study are:[68]

i. Developments involving transgenic animals now focus on recombinant proteins and medical markets rather than products for human consumption;
ii. Phenotypic selection is being replaced by genomic selection;
iii. Emerging developments in synthetic biology, metabolic engineering, genome engineering, and genome editing have potentially important implications for food and agriculture;
iv. Following a surge of patent activity in the late 1990s, the dominant trend in patent filings involving animal genetic resources of relevance to food and agriculture has been downward. However, this may change due to completion of major genome sequencing projects and the rise of new technologies such as synthetic biology, genome engineering, and genome editing;

[61] ibid 6, 7.
[62] ibid 8.
[63] ibid 8, 9.
[64] WIPO (n 48) 43.
[65] Duck, muscovy duck, zebu cattle, auroch cattle, taurine cattle, water buffalo, pig, sheep, goat, horse, donkey, bactrian camel, dromedary camel, llama, alpaca, chicken, and turkey.
ibid.
[66] ibid 9-10.
[67] ibid 10-11.
[68] ibid 5-6.

v. Much of patent activity focuses on dominant breeds and does not involve genetic material from rarer breeds from specific countries or the use of TK;
vi. There is no 'evidence of patent activity that could be considered to constitute potential biopiracy in the form of misappropriation of genetic material without the knowledge or consent of a country of origin' and 'of the use of traditional knowledge in the documents reviewed in the research;'[69] and,
vii. The data collected 'reflects the reality that traditional knowledge with respect to animal genetic resources is not presently recognised as important by patent applicants.'[70]

These conclusions are particularly relevant for two reasons. First, the report is part of the WIPO Development Agenda project 'Developing Tools for Access to Patent Information,' aimed at the compilation of information on the patterns of patenting and innovation activity related to specific technologies in various domains.[71] As such, it is highly likely that it has been used as a source of information during the meetings conducted within this organisation, which include discussion of the distribution of benefits derived from GR and TK in patent activities. Second, its conclusions contradict a vast number of claims regarding the feasible use of GR and TK in patent activity. Therefore, such results can be a politically sensitive issue. For the previously mentioned reasons, it is important to read the report of this study with caution. In this regard, two evident failures in the drafting of the conclusions can be outlined.

First, the most important aspect is that the information used for this study 'was reviewed by text mining patent applications.'[72] This is relevant because, as has been repeatedly pointed out throughout this thesis, the patent system does not incorporate any ABS obligation (PIC, MATs, and benefit-sharing) or the commitment to disclose the source of origin of the resources used in the invention. So far, the criticism on this point has led to new negotiations regarding the possibility of integrating the disclosure of origin as another requirement for patent applicants. Thus, from the information disclosed in patent documents, it cannot be affirmed that all GR used in patent activities were accessed with the PIC of the country of origin and that no TK had been used (conclusion vi), because that information is not part of patent documents.

Second, in a similar way, it cannot be claimed that 'the majority of patent activity focuses on dominant breeds and does not involve genetic material from rarer breeds from specific countries or the use of TK' (conclusion v). This, because the subject matter of this study are the species most commonly used for food and agriculture, it does not include rare, endemic, promising, and other distinct species. Likewise, from the information found in the patent documents analysed, it is not possible to conclude that developers are not interested

[69] ibid 128.
[70] ibid 14.
[71] WIPO, 'Patent Landscape Reports' <http://www.wipo.int/patentscope/en/programs/patent_landscapes/> accessed 31 March 2017.
[72] WIPO (n 48) 128.

in different breeds or TK than those reported, because this research did not search for all animal species used for breeding but focused only on seventeen, which happen to be the most commonly used in animal breeding for food and agriculture. Moreover, the FAO recognises that animal domestication (selection of animals for food, fibre, draught, and other agricultural uses) has 'resulted in thousands of genetically diverse breeds of domestic animals adapted to a wide range of environmental conditions and human needs.'[73] Given this fact, it is unlikely that scientists have no interest at all in the species domesticated by ILCs.

In spite of these flaws, it should be acknowledged that the report contains information useful to understanding the trends in patent activities about animal species most frequently used for food and agriculture:, its conclusion regarding the possible change in patent activities due to completion of major genome sequencing projects and the use of new technologies (synthetic biology, genome engineering, and genome editing). This is because it evidences the possibility of obtaining patent rights over inventions developed using technologies that allow the utilisation of GR without the need of accessing the resource. As explained in Section 3.3 of Chapter 3, this situation was not a part of ABS.

3.3.3 Study No. 3

Finally, according to the Record Year for International Patent Applications the total of applications in 2016 was 233,000; 7.3% more than in 2015.[74] The countries with the largest number of PCT applications were the USA (56,595), Japan (45,239), China (43,168), Germany (18,315), Republic of Korea (15,560), France (8,208), the UK (5,496), the Netherlands (4,679), Switzerland (4,365), and Sweden (3,720). The highest concentrations of PCT patent applications were in Asia (47.4%), followed by Europe (25.6%), and North America (25.3%). The top 10 companies making applications consist of seven companies from Asia and three from the USA, while the top 20 educational institutions comprised 10 USA and 10 Asian universities. The largest PCT applications were in digital communication (8.5%), followed by computer technology (8.2%), electrical machinery (6.9%), and medical technology (6.8%). It is striking that China has been experiencing a double-digit growth every year since 2002. If China maintains that growth, it will be the country with the largest number of patent applications within two years. This, together with the fact that China is also a wealthy country in terms of traditional medical knowledge, is a factor that could change the international emphasis on the importance of the use of TK within the patent system.

[73] FAO, 'Harvesting Nature's Diversity' <http://www.fao.org/docrep/004/v1430e/V1430E00.htm> accessed 2 April 2017.

[74] WIPO, 'Record Year for International Patent Applications in 2016; Strong Demand Also for Trademark and Industrial Design Protection' (2017) <www.wipo.int/pressroom/en/articles/2017/article_0002.html> accessed 31 March 2017.

3.4 The fair and equitable distribution of benefits in patent activities

In general terms, the concession of IPRs is supported on equity grounds. Receiving returns on the investments made to produce an invention is considered fair. Such compensation is expected to constitute an incentive for the development of further inventions. This, in theory, would be for the benefit of humankind. The same idea is expressed in almost identical terms to support the granting of IPRs for inventions based on living entities. It is claimed that IP protection promotes research that increases plant genetic variability to be used to breed thousands of varieties of food crops and domesticated animals.[75] Thus, the concession of IPRs is defended based on the idea that IP establishes a sort of creative circle, since the protection of inventions stimulates the production of more inventions, from which humanity ultimately benefits. Allegedly, the fairness of the patent system is found in the protection of the interests of all participants, creators and consumers. Because creators benefit from the protection of their inventions and the entire society, in turn, enjoys the technological and cultural developments protected with IPRs.

Nevertheless, when it comes to ABS, for example, Dutfield noted that, in practice, patents rarely shield the collective interests of all partners in bioprospecting activities. On the one hand, the poverty of many ILCs puts them in a situation of extreme vulnerability that makes it easy to exploit them. On the other hand, once natural resources are taken outside the countries of origin without their authorisation, their use becomes difficult to control.[76] To this last argument it could be added that providers depend on the users' information to know the ways in which their resources are used. Such disclosure allows benefit-sharing rather than the way in which GR is subsequently shared, either authorised or unauthorised. Because of this, Dutfield concludes that the patent system is 'unhelpful in promoting fair and equitable benefit sharing.'[77]

In addition to these arguments, it should be noted that IPRs and ABS have different interests and viewpoints, and so the concept of fair and equitable in the CBD is different from TRIPS. As explained in Section 5.2 of Chapter 4, the concept of fair and equitable sharing of benefits of the CBD is commonly used in international environmental agreements to provide a 'commonly accepted operational framework for addressing cooperation, compliance and the appropriate use of international transboundary resources.'[78] Fairness is connected with the unjust situation previously faced by providers inasmuch as they had no right to be compensated for the use of their resources. Equity is linked with the amount of money that should be shared with providers of GR and TK.[79] Accordingly, for Campbell and Hanich, the

[75] FAO (n 173).
[76] Graham Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (Earthscan 2004), 48.
[77] ibid
[78] Brooke Campbell and Quentin Hanich, 'Principles and Practice for the Equitable Governance of Transboundary Natual Resources: Cross-Cutting Lessons for Marine Fisheries Management' (2015) 14 Maritime Studies 1, 3.
[79] CBD, Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity, 'Development of Elements of Sui Generis Systems for the Protection of Traditional Knowledge, Innovations and Practices' (2007) UNEP/CBD/WG8J/5/6, 9.

concept of 'fair and equitable distribution of benefits' of the CBD is related to the distributive aspects of social justice. Therefore, to achieve a distribution of benefits that can be considered fair and equitable, the asymmetries between providers and users regarding wealth, power, capacity, and need must be considered in addition to the economic value of the resources.[80]

Considering the particular characteristics of the parties when negotiating the terms for a distribution of benefits has the potential to change the balance of valuation of GR and TK in favour of providers. This because the recognition of their contributions in the preservation and improvement of biodiversity might be taken into account for the valuation of GR and TK, which are usually considered as merely raw materials.

3.5 Accessions of GR through the Multilateral System (MLS)

As explained in Section 2 of Chapter 5, the MLS is an information system regarding the plant GR that are stored in *ex-situ* collections around the world.[81] For the sharing of plant GR, information plays a key role in providing the precise location of the resources. The MLS can be seen as the biggest initiative for the global distribution of GR in a coordinated manner.

According to the information available in the MLS, as of 31 October 2016, Easy-SMTA (an online non-mandatory application that assists users in the generation of Standard Material Transfer Agreements (SMTA)) had 1,272 users with 5,985 unique recipients of material worldwide. 48,313 SMTAs made agreements with providers located in 35 countries, and the plant GR was distributed to recipients based in 175 countries. Over time, these SMTAs had transferred 3.25 million accessions.[82] In other words, the samples provided by 35 countries are stored in collections located in another 175 countries, which have provided samples of these resources 3.25 million times. This example serves to show the efficiency of the MLS to distribute plant GR to users around the world. These 3.25 million accessions to plant GR originating from 35 countries, contrasted with the 149 contracts/permits on ABS issued by 12 countries (see Section 3.1 of Chapter 2), seems a clear indication that GR is highly used and their access is primarily carried out through the MLS. Additionally, this information indicates that a small group of countries are the main providers of a vast amount of plant GR. This, therefore, may justify that the benefits derived from their utilisation should be directed primarily towards providers.

[80] Campbell and Hanich (n 78) 3-4.

[81] FAO, 'International Treaty on Plant Genetic Resources for Food and Agriculture. The Multilateral System' <http://www.fao.org/plant-treaty/areas-of-work/the-multilateral-system/overview/en/> accessed 31 October 2017.

[82] CBD, COP-MOP, 'Update on recent developments under the International Treaty on Plant Genetic Resources for Food and Agriculture of relevance to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation' (2016) UNEP/CBD/NP/COP-MOP/2/INF/10.

4. Proposals to tackle the existing issues regarding TRIPS and ABS

Over time, conflicts related to sovereignty rights over GR and TK, and the rights of providing countries and ILCs to benefit from the use of their resources, have become evident. In addressing these concerns, two approaches have been proposed within the international fora dealing with ABS: the national-based approach and the disclosure approach. The first suggests the use of national solutions, including ABS laws and contract law, while the second recommends the inclusion of a disclosure requirement in IP applications. It has proved an intractable problem whether to leave ABS compliance to be resolved at the national level or to attempt a global solution involving incorporation of a disclosure requirement in patent applications. Since these proposals go to the very heart of the research questions of this thesis, a summary is provided below.

4.1 National-based approach

According to this approach, ABS compliance can be achieved outside the IP system through the development of national legislation incorporating the objectives of the CBD, including the use of permits, contractual obligations, and civil and/or criminal penalties for non-compliance. Regarding the erroneous concession of IPRs, has been suggested that national systems can contain the obligation to provide information about the material sought to be protected, post-grant opposition, re-examination and revocation proceedings, along with the creation of databases of TK available to patent examiners.[83] In general terms, it is stated that a nationally-based approach would:

i. Provide a balance between the value attributable to GR and TK and to that attributable to the efforts of inventors and developers of plant varieties;
ii. Be appropriately tailored so as not to have negative consequences on the IP system;
iii. Provide penalties against those violating the ABS law;
iv. Be put in place immediately;
v. Have the potential to clarify definitions of terms that may not be so clear in the CBD and the Nagoya Protocol; and
vi. Use contracts that can control access, utilisation and benefit-sharing of GR and TK.

Opponents of this proposal point out the difficulties of achieving compliance with ABS through a national approach. Among the main factors identified as the reasons for this are: (i) the transboundary nature involving the acquisition of resources in one country and the seeking of IPRs in another;[84] (ii) the limited capacity of national laws and contractual arrangements

[83] WTO (n 21) 14-16.
[84] ibid 23.

developed in accordance with those national laws to achieve compliance with ABS, because they would only be useful if their obligations are mandatory and enforceable across borders;[85] and, (iii) that actions considered to be legal under one jurisdiction could be illegal in another.[86]. In addition, the fact that there is no obligation in international law for all countries to legislate on ABS has been highlighted.[87] Thus, ABS will be even harder to achieve within countries without ABS laws.[88]

Accordingly, it has been stressed that if national laws and the contracts correspondingly developed provide sufficient means for ensuring the respect of rights, it is unclear why a different logic is applied to the protection of IPRs, where legislation applies even in the absence of contracts, and an international agreement with a strong enforcement capacity has been created to protect IPRs worldwide.[89] Moreover, it is evident that a national contract-based system with an international outlook is already in place, yet incidents of erroneous concession of patents and other conduct that might be considered as misuse/misappropriation/biopiracy of GR and TK are increasing.[90] For those who oppose the national-based approach, these are some of the reasons that justify the creation and implementation of an international binding instrument for achieving compliance with ABS.

4.2 Disclosure approach

Overall, defenders of this approach seek the establishment, in patent applications, of the obligation to disclose the origin of the GR and TK used for the development of the creation for which protection is sought. To this end, amendment of the TRIPS Agreement, and/or the Patent Co-operation Treaty (PCT), and/or the introduction of a general 'mandatory disclosure' requirement to be applied to all patent applications have been suggested. All of these proposals condition the acquiring of patent rights on:[91]

i. Revealing the source and the provider country of origin and traditional community of origin;[92]
ii. Providing evidence that PIC was obtained from the competent authorities under the relevant national regime; and

[85] ibid
[86] ibid
[87] ibid 24.
[88] ibid
[89] ibid
[90] ibid 25.
[91] ibid 27-34.
[92] Under the PCT disclosure proposal, the disclosure obligations would be triggered for patent applicants applying for patents in a Members' jurisdiction whenever they are the country of origin of the resources used in the invention. While, for the mandatory disclosure proposal, the disclosure would be an obligation only when the use of a GR or TK has been necessary for the development resulting in the invention.
ibid 31, 33.

iii. Providing evidence that fair and equitable benefit-sharing has been done according to the terms mutually agreed under the relevant national regime.

Supporters of this approach argue that a disclosure obligation would increase transparency regarding access to GR and TK while helping countries and ILCs of origin to track and monitor compliance with ABS.[93] Further, it would also contribute to a more efficient implementation of the CBD and improve the functioning of the patent system, as additional information would be available to patent examiners, including TK recorded only orally and/or TK outside of the scope of established databases. In this way, the implementation of a disclosure obligation would contribute to confidence-building that the patent system works in an equitable manner for all stakeholders.[94] The need to clarify how the disclosure requirement would work for resources obtained from *ex-situ* sources has also been mentioned.[95]

For ensuring that the disclosure requirement becomes binding on WTO Members, it has often been recommended that there be the inclusion of an Article 29bis in TRIPS. Article 29 establishes the obligation to 'disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.' Thus, such Article 29bis would add the obligation 'to disclose the source providing the biological material and TK.'

Nevertheless, because some countries are not keen to agree on limitations to patent concession, or on the application of remedies for non-compliance (such as revocation or invalidation of patents), it seems that the implementation of this approach would be hard to achieve.[96] Moreover, there is uncertainty about the possible negative effects that including compliance with ABS in the patent system may have over technological development. For this reason, it has been proposed that the problem of misappropriation of TK should be dealt with outside the patent system.[97]

5. Conclusions

The concession of IPRs over creations using GR and TK is the point connecting ABS with IP. It is constantly affirmed that the different approach to ownership rights over GR is the primary cause of the problem for the joint implementation of the CBD and IP law. This is because the CBD recognises States' sovereign rights over GR while, under TRIPS, private rights (IPRs) can be granted over creations based on GR and TK. Nevertheless, what might be the real cause of conflicts between the ABS and the IP systems is the fact that non-compliance with the ABS obligations does not affect the granting of IPRs. This problem is more serious because IP

[93] ibid 34.
[94] ibid 35.
[95] ibid 44.
[96] ibid 47.
[97] ibid 47-48.

law does not provide protection for TK and for the plants/plant varieties created/improved through the application of traditional breeding processes.

At the international level, the ABS system is a fragmented and complex regime. In this sense, countries exhibit overlapping memberships to the many international organisations, legal institutions, and spheres of legal practice (each possessing their own principles and institutions) where the relationship between ABS and IP is discussed, negotiated, and agreed. This means that the solution to the same problem is sought at the same time by the participation of the same Parties in different forums, each of them having particular interests and their own political agenda. This fact also seems to constitute an obstacle for the countries to advance in any solution on the matter.

Another issue that could be affecting ABS compliance is the consideration of GR (and biodiversity in general) and TK as raw materials with little (if any) commercial value. This argument is commonly expressed to avoid or minimise the obligation to comply with ABS. Such a consideration may negatively influence users' attitude towards ABS compliance and the benefits they are willing to distribute with providers. However, contrary to what is claimed, different studies about the utilisation of GR and TK evidence their value and show that, despite R&D being directed towards a particular spectrum of natural resources, their economic exploitation produces substantial annual profits. In the same direction, these studies show that TK is a valuable resource, which generates important profits in the pharmaceutical and medical fields. Therefore, it is not true that GR and TK are resources of no commercial value.

Because of the problems regarding the joint implementation of the CBD and TRIPs, complexity and fragmentation of the international ABS system, and the arguments about the limited commercial value of GR and TK, there is well-founded suspicion that GR and TK could occasionally be used outside ABS (without complying with PIC, MAT, and the distribution of benefits), particularly, through the MLS in the case of GR. To overcome this possibility two solutions have been proposed. The strengthening of national laws on ABS, and the inclusion of a disclosure obligation for IP applicants.

CHAPTER 7. Conclusions

1. Introduction

The aim of the present research was to examine ABS to determine what key elements are required for feasible implementation. To answer this question, each chapter of the thesis studied a different aspect of ABS: (i) the way the Parties to the CBD and the NP have developed national laws on ABS and how application of those laws is reflected in MATs; (ii) how ABS was designed in the CBD and the NP, and how their final texts are the result of a process highly influenced by the political decisions made at an international level; (iii) the manner in which the core elements of ABS could be understood; (iv) the way in which the ABS system of the CBD is interconnected with the ABS systems of the FAO and the WHO; and, (v) the way in which ABS relates to IPRs.

From the contents of these chapters some conclusions can be offered. First, the major obstacles for the implementation of ABS are caused by the way it was designed, specially its national/bilateral approach, its failure to integrate GR *ex-situ* into the system, and the absence of considerations regarding the public domain. Second, at least for now, it does not seem that the Parties to the CBD and the NP would be able to reach new agreements on ABS-related matters different from the existing ones. Third, the FAO and the WHO have ABS mechanisms in place that could provide practical information useful for the implementation of ABS under the CBD and the NP. Fourth, some solutions have been proposed from academia, but it appears that some of them have not been taken into consideration in the international fora where ABS is discussed.[1] Fifth, the practical experience gained by some countries from the implementation of national laws on ABS offer some helpful insights on possible ways in which ABS processes could be better conducted.

Based on the foregoing, the following sections present the conclusions of each of these subjects, and, finally, a synthesis of the key elements useful for the implementation of ABS will be provided.

2. ABS design

As explained in Chapter 3, the Parties to the CBD and the NP could not agree on better conditions for the ABS system. Moreover, during the negotiations of the NP, the countries seemed to be aware of the problems derived from the contents of the CBD.[2] Furthermore,

[1] Joseph Henry Vogel and Manuel Ruiz, 'The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access and Benefit Sharing' (2011) 7(1) Law, Environment and Development Journal 52, 65.

[2] See for example: Stefan Jungcurt and others, 'Summary of the Resumed Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 10-16 July 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 19 July 2010, vol 9, n 527); and 'Summary of the Tenth Conference of the Parties to the Convention on Biological Diversity: 18-29 October 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 1 November 2010, vol 9, n 544); Johannes Gnann and others, 'Summary of the Ninth Meeting of

Article 10 of NP is the result of a proposal to invest the benefits derived from the use of GR located in common areas and accessed in *ex-situ* conditions in the global preservation of biodiversity. Hence, it seems that what was an idea for seeking global benefit from the use of common goods and GR *ex-situ* became something different: the creation of a parallel ABS system which should apply for resources accessed in transboundary situations, and for GR and TK for which it is not possible to grant or obtain PIC. This aspect alone shows the complexity and intricacy of the negotiations on ABS, without even taking into consideration those aspects derived from the complexity and fragmentation of the international ABS system (see Chapter 6).

Chapter 3 also demonstrated that, owing to the lack of agreement of the countries, many sensible issues have not been solved through the development of national laws. Among all the aspects having the potential to hinder ABS implementation, three constitute the most significant obstacles: (i) the national/bilateral approach; (ii) access to GR *ex-situ*; and, (iii) the assumption that publicly accessible GR and TK are in the public domain and are, therefore, free to use outside any property system. Given the impact that these aspects have on the application of ABS, it could be argued that the ABS system would not be able to work properly unless they are amended. However, because this would require new negotiations, this seems a remote possibility at present.

For that reason, it is understandable that some of the proposals created for the implementation of a GMBSM include formulas that could solve the above-mentioned difficulties, despite the fact that they are not part of Article 10 of NP. For example, to overcome the problems derived from the national/bilateral approach, those proposals tend to seek a bundle of solutions. First, the implementation of a mechanism with a global or regional reach. Second, within the given mechanism, users would pay a flat rate established by all providers by a common agreement. Third, the rate would be paid into a single system, which would collect and distribute benefits. Finally, such a system could be a fund or a collecting society. Likewise, to overcome the problems derived related to GR *ex-situ* and the public domain, the proposals are meant to apply to all GR and TK, including: (i) GR *ex-situ*; (ii) GR and TK disclosed in databases; and, (iii) TK widely shared and dispersed.

As mentioned in Chapter 1, there seems to be nothing wrong with the proposals summarised therein. In fact, their effectiveness could only be verified through their implementation. That is to say, until they have been applied, all theoretical approaches have a level of uncertainty. Moreover, as some studies on legal transplants and legal pluralism suggest, it may be possible that the same or similar laws would produce different results in different countries. For this reason, the practical experience of ABS gained through the implementation of national laws has a dominant influence upon the conclusions of this thesis.

the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 22-28 March 2010' (Earth Negotiations Bulletin, iisd Reporting Services, IISD, 31 March 2010, vol 9, n 503).

3. Existent proposals for improving ABS

Proposals found in academic literature are rich and creative regarding the possible ways ABS could be addressed. They focus on two aspects: the identification of ABS flaws and corresponding forms to overcome them, and the development of recommendations for the creation of a GMBSM.

Regarding ABS, suggestions include (i) the use of defensive measures for preventing the improper granting of IPRs and the protection of TK; (ii) a trade secret based approach to ensure that TK is guarded and maintained undisclosed; (iii) the use of customary law both for seeking enforcement of national ABS laws at an international level and achieving benefit-sharing from the use of TK; (iv) the implementation of the domaine public payant and biocultural protocols—including the cultural objection—to obtain a distribution for the use of TK, the strengthening of national/regional laws on ABS; (v) the use of national and international courts to achieve compliance with ABS obligations, modelling of particular elements of ABS on existent international instruments e.g. MLS; and, (vi) the development of new agreements.

Although the content of all these proposals has the potential of improving ABS, the alleged benefits of a few have already been questioned by some academics. Likewise, because some of the elements were not found in the national laws reviewed in Chapter 2, the application might be difficult to achieve.

In this way, the effectiveness of the use of defensive measures and of national/regional laws and courts to achieve ABS compliance is commonly disputed. For example, it is affirmed that using GR and TK disclosed in databases not only 'serve primarily the ultimate purpose of denying entitlement claims, thus effectively transforming GR, TK and TCEs into a commons and justifying anyone's access and use of these resources' but also offers no meaningful protection against the erroneous granting of IPRs because it confers no value added to the operation of the patent system.[3] Nevertheless, the value of these databases should not be overlooked, because, at least, they could be used as proof that a given GR or TK has been previously used in the same or similar way as in the invention whose protection is sought. Therefore, they offer a possibility for opposing the patenting of an invention.

The difficulties experienced by the countries in giving full effect to their national laws in another country is apparently clear. Because of that, recommendations on the application of national/regional laws focuses on the need for harmonised systems of national laws and local ABS offices. To accomplish this, it has been proposed that national laws should ensure (i) that foreigners would have the opportunity to bring actions for ABS infractions occurring in other jurisdictions; (ii) mutual recognition and enforcement of foreign judgements and arbitral awards; and (iii) the recognition of the validity of MATs reached in different countries.[4] This

[3] Ruth Okediji, 'Negotiating the public domain in an international framework for genetic resources, traditional knowledge and traditional cultural expressions' in Daniel F. Robinson, Ahmed Abdel-Latif and Pedro Roffe (eds) *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge, London, New York, 2017), 153, 156.

[4] Sebastian Oberthür and G. Kristin Rosendal 'Global governance of genetic resources. Background and analytical framework' (ch 1) in Sebastian Oberthür and G. Kristin Rosendal (eds), *Global Governance of Genetic Resources:*

thesis agrees that deficiencies in the implementation of ABS laws are caused, among other things, both by the absence of legislative developments and a failure to enact compatible legislation among countries. For this reason, in a similar way as other authors, it considers that the best opportunity for the countries to improve ABS is through the implementation of national laws. However, this thesis does not agree with the proposed approach of creating three parallel provisions of ABS within the patent, trademark, and copyright laws.[5] This is because ABS is also related to other forms of IP protection (such as breeder's rights and designations of origin), and because, as explained in Chapter 6, fragmentation and complexity are other causes which also contribute to the limited efficiency of ABS. Thus, excluding important aspects of ABS such as the discussions involving plant breeders' and farmers' rights, and adding more fragmentation and complexity to ABS at the national level, does not seem to be the most efficient solution to this problem.

The use of national/regional courts present similar disadvantages to the application of national/regional laws. For these courts to have the power of resolving ABS-related disputes, the creation of laws and jurisdiction in the country are required. For this reason, despite some existent proposals affirming that ABS reclamations can be based upon the law of contracts or torts,[6] and that compliance with MATs can be achieved through national courts[7] and private international law,[8] this thesis considers those to be unlikely options.

Similarly, the use of international customary law, human rights and the customary law of ILCs, in practice, could face difficulties. With regard to the first, the experience of the Inter-American Court of Human Rights shows that occasionally, the countries do not comply with the judgement of the court. Therefore, it appears that winning a case before this Court does not necessarily mean achieving the distribution of benefits sought. Tvedt suggests that the reason for this is that the ABS systems need to be complemented with strong sanctions.[9] However, as expressed above, this thesis does not believe that the ultimate aim of ABS is to impose sanctions, but to achieve benefit-sharing. Because of this, and given the small level of implementation of ABS at the national level (see Figure 1 in Chapter 2), it is not clear if, in this context, a strong sanction system would effectively contribute to increased benefit-sharing.

Access and Benefit Sharing after the Nagoya Protocol (Routledge, New York, 2014) 6; Morten Walløe Tvedt, 'Beyond Nagoya: Towards a legally functional system of access and benefit sharing' (ch 9) in Sebastian Oberthür and G. Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, New York, 2014) 158-159, 172.

[5] William Fisher, 'Two Thoughts About Traditional Knowledge' (2007) 70 Law and Contemporary Problems 131–134 in Okediji (n 3) 161-162.

[6] Christine Godt, 'Enforcement of Benefit-Sharing Duties in User Countries' (Chapter 22) in Evanson Kamau, and Gerd Winter (eds), *Genetic Resources, Traditional Knowledge and the Law. Solutions for Access & Benefit Sharing* (Earthscan, 2009), 432.

[7] Hiroji Isozaki, 'Enforcement of ABS Agreements in User States' (ch 23) in Evanson Kamau, and Gerd Winter (eds), *Genetic Resources, Traditional Knowledge and the Law. Solutions for Access & Benefit Sharing* (Earthscan, 2009), 441.

[8] Claudio Chiarolla, 'The Role of Private International Law under the Nagoya Protocol' (ch 4) in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges* (Legal Studies on Access and Benefit-sharing, v. 1, BRILL Nijhoff 2012), 424.

[9] Tvedt (n 4) 165.

Regarding the use of the customary law of ILCs, based on the complexity and fragmentation of the ABS system (see Chapter 6), this thesis considers that each country should design and implement a single and uniform process for the obtaining of PIC and the adoption of MATs with ILCs. Such a system should be based on the principles contained in the ILO Convention 169 about prior consultation. The reasons for this are (i) many provider countries are also Members of that Convention,[10] meaning that their national processes will be based on the same principles, requirements and steps; and, (ii) because there is a huge amount of case law in this field at both the national and international level, countries and ILCs may be more certain about how to proceed. The same comments apply for the implementation of biocultural/community protocols and cultural objection.

As indicated earlier, the proposals from academia contain few proposals that have not been included in any of the laws reviewed. These proposals are the trade secret based approach and the domaine public payant.[11] This fact could indicate that the countries have not considered these options or, having considered them, decided not to implement them. Whatever the case, this thesis does not believe that a trade secret based approach would be easy to implement. This is because, as noted by the author of this proposal,[12] it would require the development of the ILCs' capacity building (i) to work in a coordinated way with other ILCs, (ii) to understand different concepts of IP that may be unfamiliar to them, and (iii) to be able to negotiate MATs including confidentially clauses. Additionally, TK would have to be incorporated within the unfair competition framework.

In regards to the domaine public payant, it should be noted that this has been used by some African countries as a way to obtain benefits from the use of traditional cultural expressions. This is an important aspect to consider, because unlike TK, the immaterial cultural expression should be fixed or contained on material support (e.g. a mask) for its use. This way, controlling the access and use of these expressions is different to controlling the access and use of knowledge. The material component is what allows one to track and identify the use of traditional cultural expressions. As this is not the case for TK, it would be possible that the domaine public payant could not be implemented for it, in which case a tariff system would be a better option.

Finally, this thesis agrees with those academics proposing the use of international instruments or existing instruments such as the MLS of FAO[13] to integrate a single ABS system

[10] See information available at:
<< https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:11300:0::NO::P11300_INSTRUMENT_ID:312314>> accessed 20.07.2019

[11] Manuel Ruiz, 'The legal protection of widely shared and dispersed traditional knowledge' in Daniel F. Robinson, Ahmed Abdel-Latif and Pedro Roffe (eds) *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge, London, New York, 2017), 128-129.

[12] ibidem

[13] Brendan Coolsaet, Tom Dedeurwaerdere, John Pitseys, 'The Challenges for Implementing the Nagoya Protocol in a Multi-Level Governance Context: Lessons from the Belgian Case' (2013) 2(4) Resources 555, 573-574; Tomme Rosanne Young, 'An International Cooperation Perspective on the Implementation of the Nagoya Protocol' (ch 5) in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-*

that could reduce the negative effects of having a fragmented system, and who affirm that new negotiations for the creation of regional patent systems[14] or ABS framework agreements between willing governments,[15] are possible ways to improve ABS. However, as mentioned before, it is unclear whether the countries will enter into new negotiations and if so, whether they could reach new agreements. Thus, despite the opportunities to enhance ABS through new negotiations, this seems unlikely to occur in the near future.

As for the design of a GMBSM, academics suggest implementing a handful of options: a cartel of provider countries, rents, bounded openness, common pools, a global biocollecting society, the development of new agreements for regional mechanisms or for a global solution, the establishment of fixed tariffs, and the use of funds.

As mentioned before, all these proposals have the potential to improve the functioning of ABS. However, their implementation would require that the countries reach new agreements on matters on which they could not agree during the negotiations of the NP. For this reason, at least for now, it seems unlikely that these solutions will be sought. For example, bounded openness or common pools, which are based on the same general principle that concedes unrestricted access to GR, would operate, in the first case, under a fixed rent system to be established by common agreement of provider countries, and, in the second case, by the obligation to feed the R&D results into the pool. This second option also considers a later stage for the commercial use of the resources taken from the pool which requires user confirmation. In other words, it would operate in the same way as ABS has been designed in the CBD. The difference between the common pool proposed and the CBD is that in the first case, unrestricted access is permitted by default. A logical concern is why something that has not properly worked in the CBD will work in the case of common pools.

Regarding bounded openness, it is not clear if provider countries would be able to form a single block to provide GR and TK, and to what extent this would be accepted by user countries. Another question is how useful this would be, given that the line between provider and user is not always straightforward, and that the challenges posed by the use and development of new technologies do not always require physical access to the GR.

The global biocollecting society is a different alternative to the funds, and consists of a private organisation, based on copyright collecting societies, but rather than having many collecting societies at the national level, there will be only one global collecting society, whose resources arise from the payment of voluntary contributions and funds from the World Bank. Donations will be encouraged through the provision of essential ABS services such as monitoring the use of the resources, help with licence agreements (MATs), functioning as a

Sharing in Perspective: Implications for International Law and Implementation Challenges (Legal Studies on Access and Benefit-sharing, v. 1, BRILL Nijhoff 2012), 464. 465.

[14] Ikechi Mgboji, Global Biopiracy : Patents, Plants, and Indigenous Knowledge (UBC Press, 2005) 195.

[15] Jorge Cabrera Medaglia and Cristian López Silva, 'Addressing the Problems of Access: Protecting sources, while giving users certainty' (IUCN Environmental Policy and Law, Paper No. 67/1 2007), 65; Tom Dedeurwaerdere and others, 'Governing Global Scientific Research Commons under the Nagoya Protocol' (ch 13) in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges* (Legal Studies on Access and Benefit-sharing, v. 1, BRILL Nijhoff 2012), 410

repository of documents, and as a dispute resolution institution, among others. Although this is a good idea, the functioning of this bio-collecting society largely depends upon its membership. For this reason, instead of a private organisation, it would be better to have the mechanism enshrined in Article 10 of the NP. Also, as in the case of copyright collecting societies, it would be beneficial to have a responsible authority in each country for collecting and distributing the benefits.

Finally, as already mentioned, fixing tariffs for the use of GR and TK require agreement among all Parties to the CBD and the NP.

4. The MLS of FAO and the PIP Framework of WHO

As explained in Chapter 6, the possibility that access to GR is largely happening through the MLS of the FAO appears to be confirmed from the data revealing its number of accessions. In 2016, samples from 35 countries were stored in collections located in 175 countries which permitted access 3.25 million times. This figure contrasts sharply with the 149 MATs subscribed to under the ABS system of the CBD, as revealed by the information on the ABSCH through to 15 March 2018.

From another point of view, the fact that the MLS was used 3.25 million times during 2016 could be considered a success. The global nature of the MLS appears to be the key aspect for such a success. The MLS is the biggest initiative for the global distribution of GR; its Benefit-sharing Fund (a global fund) had directly invested in projects supporting farmers in developing countries; and its Global Information System offers the fullest possible information on the plant GR of the MLS. Its weak aspect seems to be its online voluntary system to achieve compliance. For example, although the MLS has 144 State Parties through October 2017, only 19 countries submitted their reports on compliance. Despite this, it is a fact that the MLS has been able to support farming projects in different countries for a number of years. This being the case, for this thesis, such a fact should not be underestimated. Thus, a benefit-sharing scheme including mandatory sharing of non-monetary benefits and voluntary sharing of monetary benefits should be considered for the ABS system of the CBD.

For its part, the distribution of benefits occurring through the PIP Framework of the WHO seems to work for two principal reasons: (i) it is based on SMTAs (Standard Material Transfer Agreements) which consist of legally-binding agreements between the WHO and the Parties providing and receiving biological samples; and (ii) the Party in breach of contract obligations will not receive the vaccines required to face a given pandemic situation. In contrast, a different circumstance is experienced by users of GR and TK, because they do not have an urgent need to receive something in exchange for benefit-sharing. However, all laws reviewed in Chapter 2 included the suggestion to create a certification system that could serve as a proof of legal access. It is, therefore, possible that this is a common perceived need by the countries. In this way, establishing a certificate of compliance, which will be only delivered after distributing the benefits, may be a motivation that can help to increase the number of benefits received by providers of GR and TK.

From these practical experiences, it would be possible to affirm that an ABS mechanism should have: (i) a certain level of international reach; (ii) a standardised, efficient, and clear processes for accessing the resources and the sharing of benefits; and, (iii) the capacity to enforce compliance with MATs.

5. Countries' ABS implementation through national laws

Despite the fact that implementation of ABS is low and usually incomplete, ABS measures provide useful information from which some conclusions can be drawn. As perhaps expected, national laws reflect the specific characteristics of each country. In this regard, similar trends are observed between provider countries, which, at the same time, are different from those experienced among user countries.

For example, provider countries are more likely to establish 'access' activities as the aspect which triggers the obligation to distribute benefits, rather than the 'use' of GR and TK. This may be explained by the fact that once access is granted, controlling the use of the accessed resources is difficult to achieve. Therefore, by establishing ABS obligations from the 'access' activities rather than from the 'use' of the resources, the countries could have a little more of control over their resources. The ABS concepts are usually interpreted in a broad sense, so that they often include elements other than GR and TK, albeit related to them, such as: biological resources, biochemical elements, by-products, derivatives, genetic heritage, viruses, cell cultures, information of GR and TK in databases, and GR and TK in the public domain. These processes tend to specify the obligations of users regarding the need to obtain PIC and agree MATs and, occasionally, they also establish the amount of money and kind of benefits to distribute. Moreover, they contain a set of relatively common rules regarding the requirements for the obtaining of authorisations of access/use of GR and TK, such as the participation of nationals in research activities, the transfer of scientific knowledge and technologies, and the disclosure of the origin of the resources in scientific publications, among others. All provisions contain two stages: one for non-commercial utilisation and a second for the commercial use of the accessed resources. The latter sometimes involves the obtaining of a new PIC, and always requires a new MAT for the agreement of the benefits to distribute. Almost always, the sharing of samples of GR or TK is forbidden, and when that is not the case, a new PIC, authorisation, or a different ABS process is needed. These new MATs usually regulate TK utilisation and the consequent benefit-sharing. Sometimes ABS provisions recognise the property rights of ILCs over their TK and their right to grant PIC when the GR for which a permit of access is asked for is found in their territories.

For their part, in user countries' laws, 'utilisation' is often the aspect triggering ABS obligations. These laws also tend to show a restrictive interpretation of the ABS concepts and usually clarify that they will only apply for GR and TK as described in the CBD. In general terms, they expressly exclude from the ABS scope subject matters such as GR used as commodities, derivatives, information, synthetic nucleoid, and GR and TK accessed before the NP. User countries tend to be more specific with respect to the cases when an ABS obligation could

exist. Despite all this, these laws acknowledge that ILCs' rights must be respected when accessing TK, no measures with specific instructions about the process or the way ILCs' rights should be respected could be found.

In addition to the differences observed between providers and users' laws, some similarities were also identified. All laws reviewed contain different processes for commercial and non-commercial utilisation, with fewer requirements for non-commercial activities. Another similarity is that, there seems to be facilitated access for GR *ex-situ*. In some cases, such access only requires a formal communication with the national authority; in others, the use of MTAs are needed, and in some instances, the subscription of MATs for the distribution of benefits is also required. This means that, despite the fact that all countries employing measures of this kind appear to stipulate facilitated access for GR *ex-situ*, such access is not always free of monetary obligations. Moreover, according to some provisions, part of the money collected should be directed towards the *ex-situ* collection acting as the provider of the resource. All countries seem interested in having in place a system that could provide assurance of the legal access and utilisation of GR and TK. Though not implemented, all mention an internationally recognised certificate of compliance (not necessarily using these exact words), and some mention the creation of inventories for the sharing of information among national authorities, an obligation to disclose the origin of the resources, certificates of fair trade, and a barcode system.

Some sensitive issues where agreement seems difficult are: the use of GR *ex-situ*, instances where TK is widely shared and dispersed, and the expansion of the ABS scope to cover aspects other than those contained in the CBD and the NP; in particular, those linked to the use of GR and TK in biotechnology activities and the inclusion of related information in databases. Given the difficulties that the countries seem to experience in finding agreement on these issues, it is advisable that they are left aside from the negotiations in the creation of a GMBSM. The Parties to the CBD and the NP could continue their work in the search for agreement and solutions on these matters after establishing the GMBSM and, if any kind of agreement is achieved, there should be no problem in adjusting the mechanism.

No regulation was found specifically suggesting how to implement Article 10 of the NP. However, some laws include measures on aspects identified in the academic literature as cases where GR and TK could be considered in a transboundary situation, i.e., GR *ex-situ* and GR and TK or their information in the public domain. All laws reviewed contain rules about international cooperation that leave open the possibility for future development of international instruments. Interestingly, from the texts of the laws analysed, it is not possible to know what countries understand as fair and equitable because these concepts are, at best, limited to establishing percentages of participation and specific obligations for the distribution of benefits. Therefore, there is not enough information in these laws to know what levels of monetary and non-monetary resources the countries would accept as a fair and equitable distribution of benefits. However, all laws reviewed contemplate the possibility of creating funds as a means to collect and distribute the monetary benefits derived from the use of GR and TK, while none of them contain a different alternative.

On the MATs reported to the ABSCH it is worth highlighting that: (i) despite the fact that national research institutes are the main users of GR and TK, there is a clear commercial interest in using GR and TK (62% of all MATs are for commercial uses, see Tables 4 and 5); (ii) the information provided on MATs is incomplete, so that in many cases it is not possible to determine the resource accessed, the user, the authority granting permission, or the intended use of the resource (see Tables 4, 5 and 6). This trend is predominantly observed in countries considered in this study as user countries (Bulgaria, Belarus, Malta, and Spain). Similarly, provider countries seem to be more likely to disclose information more completely (the Dominican Republic, Guatemala, India, Kenya, Mexico, Panama, Peru, and South Africa). Given this, it is possible to affirm that, in general, countries are not willing or might not have the priority to disclose information about MATs to the ABSCH. Thus, for further developments on ABS, countries should not rely exclusively on the information disclosed to this site.

6. Key elements required for a feasible implementation of ABS

Ideally, ABS operativity could be improved if more uniformity is reached among national laws. However, with the current lack of agreement on sensitive issues, it seems that the design of ABS laws will continue to reflect the countries' particular interests. For example, national laws present differences regarding the subject matter that triggers ABS obligations. Additionally, from the laws reviewed in Chapter 1, it can be observed that national developments usually include a second phase to conduct new negotiations to agree on new benefits when a change in the utilisation of the resource from non-commercial to commercial has occurred. These two factors may hinder the distribution of benefits: first, because, for the provider, it is difficult to know when the use of a resource has changed, and, second, because it is difficult to obtain a distribution of benefits from the use of a resource when such an obligation does not exist for that particular resource in the country where it has been used.

For these reasons, this thesis proposes that the countries should abandon the task of controlling and monitoring all uses of GR and TK, together with the expectation of entering into individual bargains with each user. This is all well and good on paper, but could be difficult to implement in practice. Renouncing the control and monitoring the use of the resources also means that countries should abandon the idea of a mandatory obligation for the sharing of monetary benefits. Instead, this thesis considers that the establishment of mandatory obligations for the sharing of non-monetary benefits would be an obligation that all users be willing to fulfil. Therefore, this could be a feasible way to ensure that providers receive non-monetary benefits. Furthermore, because these benefits are described in nearly the same way in all the laws examined, obtaining distribution would be easy to achieve. Also, the sharing of non-monetary benefits could improve the scientific capabilities of provider countries.

Despite the above, it should be noted that the sharing of benefits happening between *ex-situ* centres and their users cannot be regarded as cases in which the parties involved are fully complying with the ABS rules. This is because, this sharing of benefits seems to be largely

occurring between *ex-situ* centres and among their users,[16] while the CBD establishes that in every sharing of benefits should be involved the country of origin, even when GR *ex-situ* is accessed. Thus, as discussed in Section 3 of Chapter 2, it seems that the only measure *ex-situ* centres should take to fulfil the obligations contained in the CBD is to ensure that the countries of origin are also the beneficiaries of the benefits distributed when such centres share samples of GR. Moreover, because the experience shows that users of biodiversity are familiar with the existing rules of *ex-situ* centres and are willing to follow them, countries should integrate those practices into their national ABS laws. Furthermore, ideally, *ex-situ* centres' ABS policies should be developed with the guidance of their national competition authorities, and these centres should be reporting on their activities to the ABSCH.

Contractual clauses in MATs are accepted by all laws studied as legitimate agreements to determine ABS obligations. For this reason, they should be used to establish the non-commercial obligations as a means to facilitate dispute resolution at an international level when necessary.

Under this proposal, the sharing of monetary benefits would be voluntary. For its promotion, the countries could provide tax benefits, as is already happening in some sectors. To promote the sharing of non-monetary benefits, the countries should use a certificate of compliance, issued only after the benefits have been shared.

This proposed solution may not be ideal nor may it even be possible to affirm that under such a scheme a fair and equitable sharing of benefits would be conducted. Yet given the experience of the MLS, for this thesis, a solution like this could be beneficial. This is because, despite criticisms,[17] the MLS has in place a similar benefit-sharing scheme which has been able to support the development of farming projects in different countries for many years. Therefore, it is possible to expect that a voluntary system such as proposed here would be able to collect economic resources that would allow the provider countries to invest in the preservation and promotion of their national biodiversity and TK.

With regard to the GMBSM, this thesis considers that this mechanism has the greatest potential to achieve benefit-sharing. For this reason, a proposal for its creation is also a part of these conclusions. The solution proposed for implementing ABS at a national level is considered to be useful for the creation of a GMBSM as well. This is because the establishment of a global mechanism for the distribution of monetary benefits requires new agreements of all Parties to the CBD and the NP on aspects such as tariffs, kind of uses, and sectors of the economy for which such tariffs would be compulsory, among others. Thus, a voluntary system could operate until such agreements are concluded.

Some aspects should not be initially included in a GMBSM. As the countries have not reached agreement regarding GR *ex-situ*, and TK widely shared and dispersed, until there is

[16] See for example: Kate Davis and others, 'An Access and Benefit-Sharing Awareness Survey for Botanic Gardens: Are They Prepared for the Nagoya Protocol?' (2015) 98 South African Journal of Botany 148

[17] See for example: Margo A. Bagley, 'De-materializing genetic RESOURCES Synthetic biology, intellectual property and the ABS bypass' (ch 15) in Charles R. McManis and Burton Ong (eds) *Routledge Handbook of Biodiversity and the Law* (Routledge, London and New York, 2018) 229-230.

clarity on how the issue of the public domain should be applied to GR and TK, the Parties to the CBD and the NP would probably not agree throughout the global mechanism. The inclusion in national laws of elements other than GR and TK as defined in the CBD might also be controversial. For instance, there is no consensus among the countries on elements such as information, genetic material that does not contain functional units of heredity, by-products, derivatives, viruses, and any other related elements. It could also be problematic that the inclusion of sanctions could affect the obtaining of IPRs or existing rights. It is possible that including any of these aspects in a proposal for the implementation of a GMBSM would obstruct the opportunity for agreement. Hence, a basic GMBSM, containing no other elements than those incorporated in Article 10 of NP as defined in Article 2 of the CBD, and containing only a mandatory obligation for the sharing of non-commercial benefits, would be easier to agree upon and implement, and could secure the sharing of non-commercial benefits and provide some money for supporting projects directed towards the preservation of biodiversity and TK.

One possible obstacle for the establishment of a GMBSM such as this is that a similar mechanism exists within the FAO. For this reason, it could be possible that users of GR and TK would not see a clear difference between the MLS and the GMBSM and, therefore, the contributions to the GMBSM could be less significant than expected. However, this should not be a concern. This thesis considers that receiving monetary benefits (even though they are less than forecasted) is better than having no benefits to invest in the preservation of biodiversity and TK. Moreover, modifications to the mechanism can be done after it has been established and, because of that, such modifications could be based on the experience about its real needs and functions. Furthermore, in the future, countries could consider the possibility of uniting the MLS and the GMBSM into a single mechanism to integrate GR and TK accessed in transboundary situations, GR and TK for which it is not possible to grant or obtain PIC, and GR accessed *ex-situ*. Also, the countries could further consider expanding the scope of this mechanism to GR *ex-situ* worldwide and widely disseminated TK/TK in the public domain.

As all countries analysed mention the possibility to create a fund, it seems clear that they will accept it as the financial mechanism for a GMBSM. In a similar way as is happening with the MLS, the funds of the GMBSM could be distributed through the financing of projects; in this case, for the preservation of biodiversity and TK. Also, as prescribed in Brazilian law, it would be useful for a portion of the fund be saved to ensure that any ILCs affected by the use of their shared TK will be compensated. However, on the contrary, as proposed for the creation of a global biocollecting society, having a national authority responsible in each country for collecting and distributing benefits, would be more beneficial.

In sum, the proposed elements for the improvement of ABS and the creation of a GMBSM are as follows:

1. For the improvement of ABS at a national level:
    a. Only mandatory obligations for the sharing of non-commercial benefits.

   b. The use of MATs for establishing ABS and the distribution of non-monetary benefits.
   c. The use of an international recognised certificate of compliance issued after the sharing of benefits has been conducted.
   d. A voluntary sharing of monetary benefits.
   e. The moneys collected should be distributed to finance projects for the preservation of biodiversity and TK.

2. Additional elements for the establishment of a GMBSM:
   a. The mechanism should have a global rather than a regional reach.
   b. Should apply to GR and TK as described in Articles 2 of CBD and 10 of NP.
   c. Should use a global fund as its financial mechanism.
   d. The fund should make national authorities responsible for collecting and distributing the benefits in each country.
   e. One part of the moneys collected should be invested in the compensation of any ILCs affected by the use of their shared TK.

Overall, this study strengthens the idea that creating operative ABS mechanisms would be possible if existing experiences are incorporated. Non-monetary benefits could be established by observing what users of GR and TK are currently sharing in the MATs agreed so far and the MTAs subscribed with *ex-situ* centres.

This thesis' main recommendation is to implement, to the extent possible, a harmonised approach through national laws, in order to create the best way forward towards addressing existent limitations on the implementation of ABS, given the current circumstances. The insights gained from this thesis may be of assistance to policymakers and countries, who could engage in a study to combine the theoretical and practical approaches to ABS implementation. In spite of these conclusions, this study is limited by the lack of information disclosed to the ABSCH in regards of national laws, the small number of MATs reported, and the little information on the ABS conditions contained therein. Also, during the research process it was observed that little information exists on ABS contractual experiences and decisions from the judiciary on these matters.

The findings stated above provide the following insights for future research:

1. A wider approach to practical experiences implementing ABS is needed, including studies of contracts and case law.
2. As explained in Section 6.1.8 of Chapter 3, Article 10 of the NP was initially intended to apply to GR located in common areas and in *ex-situ* conditions. For this reason, further research should be aimed to address that problem.

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